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NATIONAL RESEARCH INSTITUTES REAUTHORIZATION ACT OF 1988

May 26 (legislative day, May 18), 1988.—Ordered to be printed

Mr. Kennedy, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 2222]

The Committee on Labor and Human Resources, to which was referred the bill (S. 2222) to amend the Public Health Service Act to reauthorize programs relating to the National Research Institutes established under title IV of such Act, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill, as amended, do pass.

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Summary of the Bill

The National Research Institutes Reauthorization Act of 1988, S. 2222, amends the Public Health Service Act (PHSA) and makes additional provisions as follows:

1. *Biomedical and Behavioral Research Facilities.*—An extramural grants program, to be located in the Division of Research Re-

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sources, is created. Public and nonprofit research institutions may apply for grants to expand, remodel, renovate, or alter existing research facilities or to construct new ones. The grants will be subject to peer review and review by a technical advisory board which is established. Award criteria are set for both established institutions and for emerging centers of excellence. The Federal contribution is limited to 50 percent of the necessary cost, and recovery rules are set down. The authorization level is $150,000,000 for FY 1989 and such sums as necessary for FY 1990 and FY 1991.

2. Biomedical Ethics.—The NIH is authorized to enter into cooperative agreements or to award grants for the development or expansion of no less than five extramural centers of excellence in biomedical ethics. The centers will analyze, issue reports and recommendations, and disseminate information on biomedical ethical issues. The Secretary is mandated to appoint an ethics advisory board to advise the Secretary regarding research on fetal therapies and research involving human fetuses. The Secretary is mandated to contract for a study of the scientific, ethical, and funding issues surrounding medical research on fetal therapy and involving human fetuses. The National Academy of Sciences shall be invited to apply for the contract. The ban on secretarial waivers for fetal reseach is continued for two years.

3. National Institute on Deafness and Other Communication Disorders.—A new institute concerned with disorders of hearing and other communication processes, including diseases affecting hearing, balance, voice, speech, taste, and smell, is created. It replaces the Communicative Disorders program of the current National Institute of Neurological and Communicative Disorders and Stroke. A research program is set out and provisions are made for the establishment of a Data System, an Information Clearinghouse, and support of new and existing centers for studies of disorders of hearing and other communication processes.

4. Centers for Geriatric Research and Training.—The National Institute on Aging is authorized to enter into cooperative agreements or make grants for the development or expansion of centers of excellence in geriatric research and training.

5. National Center for Medical Rehabilitation Research.—A center for medical rehabilitation research is created at the NIH with specific authorities for the Director and the National Advisory Council. The Center is authorized to award grants, contracts and cooperative agreements for research and training. A comprehensive research plan in medical rehabilitation research is ordered and a coordinating committee established.

6. National Center for Nursing Research.—The authorities for NCNR are expanded to include making grants to establish demonstration projects for the development and evaluation of innovative models for hospital nursing care to improve the recruitment and retention of personnel and the quality of the inhospital nursing role. NCNR is also granted construction authority.

7. National Cancer Institute.—The authorities are reaffirmed with minor changes in the authority of the Director, and the level of authorization is set at $1,671,000,000 for FY 1989 and such sums as are necessary for FY 1990 and FY 1991.

8. National Heart, Lung, and Blood Institutes.—The authorities are reaffirmed with minor changes in information and education and the resources program. The level of authorization is set at $1,102,000,000 for FY 1989 and such sums as are necessary for FY 1990 and FY 1991.

9. National Institute of Diabetes and Digestive and Kidney Diseases.—The institute is renamed as the National Institute of Diabetes, Digestive and Kidney Diseases, and Endocrinology. The termination provision for the National Advisory Boards is deleted.

10. National Library of Medicine.—Membership of the Board of Regents is changed from 10 to 13, and members are to be appointed by the President, rather than by the Secretary. The authorization of appropriations level is set at $14,000,000 for FY 1989 and such sums as are necessary for FY 1990 and FY 1991. A new grant program for the development of new educational technologies is created, and construction authority is given in two grant programs. The restriction on award size is deleted.

11. Awards and Training.—The authorization level for National Research Service Awards is set at $350,000,000 for FY 1989 and such sums as are necessary for FY 1990 and FY 1991. Multidisciplinary research training is emphasized.

12. Biomedical Scientific Service.—The Secretary is authorized to establish a Senior Biomedical Scientific Service with enhanced compensation rates to be offered to civil service and commissioned corps employees in the fields of biomedical research or clinical research evaluation.

13. Other Technical Changes.—The Director of NIH is given authority to establish scientific program advisory committees. Technical changes are made concerning the powers and duties of the directors of institutes and agencies of NIH, and concerning national advisory councils. Minor wording changes are made in the description of the National Institute of Arthritis and Musculoskeletal and Skin Diseases. Technical changes are made in peer review requirements.

BACKGROUND AND NEED FOR LEGISLATION

The National Research Institutes Reauthorization Act of 1988 revises and extends a number of programs under the Public Health Service Act relating to the National Institutes of Health. NIH is the principal medical research arm of the Federal Government, with the mission of improving the health of the Nation by increasing our understanding of the processes underlying human health and by acquiring new knowledge to help prevent, detect, diagnose, and treat disease.

The bill extends for three years the authorization of appropriations for the two largest institutes, the National Cancer Institute and the National Heart, Lung, and Blood Institute. For FY 1989 the authorization levels have been increased to allow some real growth above current appropriations, and have been left open on a "such sums" basis for FY 1990 and FY 1991. Research advances have been building in both these areas and deserve continued strong support.

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Three-year authorizations are also made for the National Research Service Awards and the Medical Libraries Assistance Act programs of the National Library of Medicine. NRSA training grants and fellowships are essential to the development of necessary skilled biomedical manpower. There has been essentially no growth in the number of trainees in the last 10 years, while the size of the biomedical enterprise has grown substantially. The authorization provided for FY 1989 is a 27 percent increase over the previous level, which will allow for growth and for meeting increased costs by raising stipends. The FY 1989 authorization for the medical libraries grant program is maintained at the same level as FY 1988, still substantially greater than the current appropriation. NLM programs provide development of information specialists and library resources in critically-needed support of the nation's biomedical researchers.

A major feature of the bill is the establishment of a matching grants program at the NIH in the Division of Research Resources for construction and maintenance of biomedical and behavioral research facilities. Since the Health Research Facilities Act of 1956 ran out in 1972, the NIH has been without general construction authority, and categorical authorities for NCI, NHLBI, and NEI did not receive appropriations for 1988. Dwindling Federal support over the last 16 years has resulted in a backlog of needed construction and maintenance. Research administrators have sought to maintain research progress by protecting people and equipment, at the expense of facility construction and repair. Anecdotes, professional society requests, and study after study have confirmed that research is being impeded and the situation is worsening. It is also clear that in such a tight market for funds, emerging centers of excellence are at an even greater disadvantage. These are institutions which may lag behind in their institutional development or which have faced significant barriers to their development, but which have done productive research in spite of the barriers. The proposed program would begin to rebuild the infrastructure necessary for medical progress to be made at a rapid pace.

The legislation creates a new National Institute on Deafness and Other Communications Disorders, with responsibility for research on disorders of hearing and other communication processes, including diseases affecting hearing, balance, voice, speech, taste, and smell. A sizeable research program in these fields has been developed by the Communicative Disorders program of the National Institute of Neurological and Communicative Disorders and Stroke, but it is clear that more needs to be done in this area. Already in this country there are approximately 22 million Americans who experience partial or total loss of hearing, and an additional 2.3 million with speech and other communication disorders. About half of these people are over 65 years of age, and the numbers will increase as more Americans live longer. Creation of a separate institute will give focus and visibility to research addressing the needs of this special population.

This legislation also calls for the creation of a National Center for Medical Rehabilitation Research in the NIH. This important area is supported categorically in several NIH institutes. It has been more generally supported by the National Institute of Disability and Rehabilitation Research, located in the Department of Education. Researchers in medical rehabilitation research have complained that their field is misplaced in NIDRR which has a strong, appropriate vocational and educational mission. They also feel that, while the individual programs at NIH are excellent, the lack of a focal point means there is insufficient coordination of these efforts, and there is no mechanism to fund generic programs in medical rehabilitation research. The center will provide the administrative leadership necessary for this field to reach its full potential.

An important feature of this bill is the establishment of the Senior Biomedical Scientific Service. Historically, NIH has been able to attract and keep many of the very best scientists in the nation. Indeed, a tour of duty at NIH was considered by many to be mandatory for entering a biomedical research career at the cutting edge of science. That time is now past. The gap between Federal Government and university salaries for scientific personnel has grown so widely that it is now difficult for the NIH to recruit and retain the best scientists when coupled with the other limitations of working for NIH. The NIH intramural program is in danger of losing its world class stature. The proposed service would help to put NIH, FDA and CDC scientists on a fiscal parity with their nonfederal colleagues.

The bill provides authority to the National Center for Nursing Research to support demonstration projects concerning innovative models of nursing care to restructure the role of the hospital nurse. The national nursing shortage is well documented and threatens to reach crisis proportions. Part of the solution to this problem is, undoubtedly, improved pay and benefits for nurses. Another part, however, will be addressed by the demonstration projects, which will support investigations of the quality of the nursing role with regard to patient care. NCNR is also given new authority to make grants for the acquisition, construction, or renovation of facilities.

The legislative authorizes the National Institute of Aging to establish centers in geriatric research and research training. There has been an explosion of research in the aging area, and the centers would facilitate the movement of the latest advances to patients. The primary emphasis of the centers will be the training of physicians to provide instruction in geriatrics to other physicians and to students of health professions.

This bill would also establish programs to deal with the current void in bioethics. The Division of Research Resources is authorized to establish new centers for the study of ethical issues surrounding biomedical and behavioral research. A National Academy of Sciences study of issues regarding research on fetal therapy and on research involving human fetuses is called for, and an Ethics Advisory Board to clarify issues of eligibility is mandated. The advice and guidance gained from these efforts will assist in making the best use of our opportunities and resources.

TEXT OF THE BILL AS REPORTED

[S. 2222, 100th Cong. 2d Sess.]

A BILL To amend the Public Health Service Act to reauthorize programs relating to the National Research Institutes established under title IV of such Act, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

[SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

[(a) SHORT TITLE.—This Act may be cited as the "National Research Institutes Reauthorization Act of 1988".

[(b) TABLE OF CONTENTS.—The table of contents is as follows:

[Sec. 1. Short title; table of contents.
[Sec. 2. References to the Public Health Service Act.

[TITLE I—BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

[Sec. 101. Biomedical and behavioral research facilities.

[TITLE II—BIOMEDICAL ETHICS

[Sec. 201. Centers for biomedical ethics.
[Sec. 202. Fetal therapy and research.

[TITLE III—NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

[Sec. 302. Centers for the Study of Deafness and Other Communicative Disorders.

[TITLE IV—NATIONAL INSTITUTE ON AGING

[Sec. 401. Centers of geriatric research and training.

[TITLE V—NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH

[Sec. 501. National Center for Medical Rehabilitation Research.

[TITLE VI—NATIONAL CENTER FOR NURSING RESEARCH

[Sec. 601. National Center for Nursing Research.

[TITLE VII—NATIONAL CANCER INSTITUTE

[Sec. 701. Purpose.
[Sec. 702. Special authorities of the Director.
[Sec. 703. National cancer research and demonstration centers.

[TITLE VIII—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

[Sec. 801. Information and education.
[Sec. 802. Resources program.
[Sec. 803. National research and demonstration centers.
[Sec. 804. Interagency technical committee.

[TITLE IX—NATIONAL INSTITUTES OF HEALTH

[Sec. 901. Appointment and authority of the Director.

9TITLE X—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

[Sec. 1001. Appointment and authority of the directors.
[Sec. 1002. Advisory councils.
[Sec. 1003. Authorization of appropriations.

[TITLE XI—NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

[Sec. 1101. Advisory boards.

[TITLE XII—NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

[Sec. 1201. National arthritis and musculoskeletal disease programs.
[Sec. 1202. Multipurpose disease centers.

[TITLE XIII—NATIONAL LIBRARY OF MEDICINE

[Sec. 1301. Board of regents.
[Sec. 1302. Authorization of appropriations.
[Sec. 1303. Grants for the development of new educational technologies.
[Sec. 1304. Grants for basic resources of medical libraries.
[Sec. 1305. Grants for establishment of regional medical libraries.

[TITLE XIV—AWARDS AND TRAINING

[Sec. 1401. National research service awards.

[TITLE XV—GENERAL PROVISIONS

[Sec. 1501. Peer review requirements.

[TITLE XVI—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

[Sec. 1601. Biomedical research.

[SEC. 2. REFERENCES TO THE PUBLIC HEALTH SERVICE ACT.

[Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act (42 U.S.C. 201 et seq.).

[TITLE I—BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

[SEC. 101. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

[Title IV (42 U.S.C. 601 et seq.) is amended by adding at the end thereof the following new part:

[“PART H—BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

[“SEC. 499A. GRANTS FOR CONSTRUCTION.

[“The Director of the National Institutes of Health, through the Director of Research Resources (hereinafter in this part referred to as the ‘Director’), is authorized to award grants to public and nonprofit private institutions to expand, remodel, renovate, or alter existing research facilities or construct new research facilities pursuant to this part. Applications for grants shall be evaluated on the basis of merit as provided in section 499H.

[“SEC. 499B. TECHNICAL REVIEW BOARD ON BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

[“(a) ESTABLISHMENT.—

[“(1) IN GENERAL.—There is established in the Division of Research Resources of the National Institutes of Health a Technical Review Board on Biomedical and Behavioral Research Facilities (hereinafter referred to in this part as the ‘Board’) to advise the Director and the Advisory Council established pursuant to section 480 (hereinafter in this part referred to as the 'Advisory Council') on matters concerning the construction of facilities, and to conduct the peer review of applications received for this part.

[“(2) MEMBERSHIP.—The Board shall be appointed by the Director, and consist of not fewer than—

[“(A) 12 members appointed without regard to the civil service laws; and

[“(B) an official of the National Science Foundation designated by the National Science Board.

[“(3) FACTORS FOR APPOINTMENTS.—In selecting persons for appointment to the Board under paragraph (2), the Director shall consider factors such as—

[“(A) experience in the planning, construction, financing, and administration of institutions engaged in the conduct of research in the biomedical or behavioral sciences;

[“(B) familiarity with the need for biomedical or behavioral research facilities;

[“(C) familiarity with the need for dentistry, nursing, pharmacy, and allied health professions research facilities; and

[“(D) experience with emerging centers of excellence as defined in section 499C(d)(2).

[“(b) DUTIES.—The Board shall—

[“(1) advise and assist the Director and the Advisory Council in the preparation of general regulations and with respect to policy matters arising in the administration of this part;

[“(2) make recommendations to the Director and the Advisory Council concerning—

[“(A) merit review of applications for grants; and

[“(B) the amount that should be granted to each applicant whose application, in its opinion, should be approved; and

[“(3) prepare an annual report for the Advisory Council, which shall be available to the public, that—

[“(A) describes the activities of the Board in the fiscal year for which the report is made;

[“(B) describes and evaluates the progress made in such fiscal year in meeting the facilities needs for the biomedical research community;

[“(C) summarizes and analyzes expenditures made by the Federal government for such activities;

[“(D) reviews the approved but unfunded applications for grants; and

[“(E) contains the recommendations of the Board for any changes in the implementation of this part.

[“(c) TERMS.—

[“(1) TERMS.—Each appointed member of the Board shall hold office for a term of 4 years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of such term.

[“(2) STAGGERED TERMS.—Of the initial members appointed to the Board—

[“(A) three shall hold office for a term of 3 years;

[“(B) three shall hold office for a term of 2 years; and

[“(C) three shall hold office for a term of 1 year;

as designated by the Director at the time of appointment.

[“(3) REAPPOINTMENT.—No member shall be eligible for reappointment until a year has elapsed since the end of such member's preceding term.

[“(d) COMPENSATION.—Members of the Board who are not officers or employees of the United States shall receive for each day the members are engaged in the performance of the functions of the Board compensation at the same rate received by members of other national advisory councils established under this title.

[“(e) USE OF MEMBERS.—The Director is authorized to use the services of any member or members of the Board, and where appropriate, any member or members of any other national advisory council established pursuant to this title, in connection with matters related to the administration of this part, for such periods, in addition to conference periods, as the Director may determine. The Director shall make appropriate provision for consultation between and coordination of the work of the Board and the Advisory Council, with respect to matters bearing on the purposes and administration of this part.

[“(f) ADMINISTRATION.—The administration of the Board's functions shall be the responsibility of the Director and shall be carried out in the same manner as the administration of the functions of the Advisory Council.

[“(g) BOARD ACTIVITIES.—

[“(1) IN GENERAL.—In carrying out its functions under this part, the Board may establish subcommittees, convene workshops and conferences, and collect data as the Board considers appropriate.

[“(2) SUBCOMMITTEES.—Subcommittees formed under paragraph (1) may be composed of Board members and nonmember consultants with expertise in the particular area to be addressed by the subcommittees. The subcommittee may hold meetings as determined necessary to enable the subcommittee to carry out its activities.

[“SEC. 499C. APPLICATION AND SELECTION FOR GRANTS.

[“(a) SUBMISSION.—Applications for grants under this part shall be submitted no less frequently than annually to the Director by public and nonprofit private institutions.

[“(b) AWARDING OF GRANTS.—A grant under this part may be awarded by the Director if—

[“(1) the applicant institution is determined by the Director to be competent to engage in the type of research for which the proposed facility is to be constructed;

[“(2) the applicant institution meets the eligibility conditions established by the Director;

[“(3) the application contains or is supported by the reasonable assurances that—

[“(A) for not less than 20 years after completion of construction, the facility will be used for the purposes of research for which it is to be constructed;

[“(B) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility; and

[“(C) sufficient funds will be available, when construction is completed, for effective use of the facility for the research for which it is being constructed; and

[“(4) the proposed construction will expand the applicant's capacity for research, or is necessary to improve or maintain the quality of the applicant's research.

A grant under this part may be made only if the application therefor is recommended for approval by the Advisory Council.

[“(c) ELIGIBILITY CONDITIONS.—Within such aggregate monetary limit as the Director may prescribe, applications that, solely by reason of the inability of the applicants to give the assurance required by subsection (b)(2), fail to meet the requirements for application set forth in this section, may be approved on condition that the applicants give the assurance required by such paragraph within a reasonable time and on such other reasonable terms and conditions as the Director may determine.

[“(d) AWARDING GRANTS.—

[“(1) IN GENERAL.—In acting on applications for grants under this part, the Director shall take into consideration—

[“(A) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding capacity for biomedical or behavioral research and in improving the quality of such research;

[“(B) the quality of research or training, or both, to be carried out in the facilities involved;

[“(C) the need of the institution for such facilities in order to maintain or expand the institutions research and training mission;

[“(D) the congruence of the research activities to be carried out within the facility with the research and investigator manpower needs of the United States; and

[“(E) the age and condition of existing research facilities and equipment.

[“(2) INSTITUTIONS OF EMERGING EXCELLENCE.—

[“(A) IN GENERAL.—In addition to paragraph (1), the Director shall consider other criteria for the awarding of grants for the construction of research facilities to eligible institutions that demonstrate emerging excellence in biomedical or behavioral research.

[“(B) ELIGIBILITY.—To be eligible for a grant under this paragraph, an institution shall—

[“(i) have a plan for research or training advancement and the ability to carry out the plan; and

[“(ii)(I) carry out research and research training programs that have a special relevance to a problem, concern, or unmet need of the United States;

[“(II) have already demonstrated a commitment to enhancing and expanding their research productivity; or

[“(III) have been productive in research or research development and training in settings where significant barriers to institutional development have been created by—

[“(aa) the underrepresentation of minorities in health science careers;

[“(bb) the health status deficit of a large segment of the population; or

[“(cc) a regional deficit in health care technology, services, or research resources that can adversely affect health status in the future.

[“SEC. 499D. AMOUNT OF GRANT; PAYMENTS.

[“(a) AMOUNT.—The amount of any grant awarded under this part shall be determined by the Director, except that such amount may not exceed—

[“(1) 50 percent of the necessary cost of the construction of a proposed facility as determined by the Director; or

[“(2) in the case of a multipurpose facility, 50 percent of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

[“(b) RESERVATION OF AMOUNTS.—On approval of any application for a grant under this part, the Director shall reserve, from any appropriation available therefor, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with construction progress, as the Director may determine. The Director's reservation of any amount under this subsection may be amended by the Director, either on approval of an amendment of the application or on revision of the estimated cost of construction of the facility.

[“(c) EXCLUSION OF CERTAIN COSTS.—In determining the amount of any grant under this part, there shall be excluded from the cost of construction an amount equal to the sum of—

[“(1) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to be financed in part by grant authorized under this part; and

[“(2) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.

[“(d) WAIVER OF LIMITATIONS.—The limitations imposed by subsection (a) may be waived at the discretion of the Director for institutions described in section 499C(d)(2).

[“SEC. 499E. RECAPTURE OF PAYMENTS.

[“If, within 20 years after the completion of construction for which a grant has been awarded under this part—

[“(1) the applicant or other owner of the facility shall cease to be a public or nonprofit private institution; or

[“(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so);

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by agreement of the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

[“SEC. 499F. NONINTERFERENCE WITH ADMINISTRATION OF INSTITUTIONS.

[“Except as otherwise specifically provided in this part, nothing contained in this part shall be construed as authorizing any department, agency, officer, or employee of the United States to exercise any direction, supervision, or control over, or impose any requirement or condition with respect to, the research conducted by, and the personnel or administration of, any institution.

[“SEC. 499G. REGULATIONS.

[“Within 6 months after the date of enactment of this part, the Director, after consultations with the Advisory Council, shall prescribe regulations regarding the eligibility of institutions for grants awarded under this part, and the terms and conditions of approving applications for such grants. The Director may prescribe such other regulations as the Director finds necessary to carry out this part.

[“SEC. 499H. PEER REVIEW OF APPLICATIONS.

[“(a) In General.—The Director shall require appropriate peer review of applications for grants under this part in accordance with section 492.

[“(b) Manner of Review.—Review of grant applications shall be conducted in a manner consistent with the system of scientific peer review conducted by scholars with regard to applications for grants under this Act for biomedical and behavioral research.

[“(c) Membership.—Members of the peer review group established by the Director under section 499B shall be individuals who by the virtue of their training or experience are eminently qualified to perform review functions, except that not more than one-fourth of the members of any peer review group shall be officers or employees of the United States.

[“SEC. 499I. AUTHORIZATION OF APPROPRIATIONS.

[“There are authorized to be appropriated to award grants and carry out this part $150,000,000 for fiscal year 1989 and such sums as necessary for each of the fiscal years 1990 and 1991. Sums appropriated pursuant to this section shall remain available until expended.

[“SEC. 499J. DEFINITIONS.

[“As used in this part:

[“(1) Construction and Cost of Construction.—The terms ‘construction’ and ‘cost of construction’ include the construction of new buildings and the expansion, renovation, remodeling, and alteration of existing buildings, including architects’ fees, but not including the cost of acquisition of land or offsite improvements.

[“(2) Public or Nonprofit Private Institution.—The term ‘public or nonprofit private institution’ means an institution that conducts biomedical or behavioral research, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.".

[TITLE II—BIOMEDICAL ETHICS

[SEC. 201. CENTERS FOR BIOMEDICAL ETHICS.

[(a) IN GENERAL.—Subpart 1 of part E of title IV (42 U.S.C. 287 et seq.) is amended by adding at the end thereof the following new section:

["SEC. 479A. CENTERS FOR BIOMEDICAL ETHICS.

["(a) IN GENERAL.—The Director of the Division of Research and Resources shall enter into cooperative agreements and make grants to public and private nonprofit entities for the development or expansion of no less than five centers of excellence in biomedical and behavioral research ethics.

["(b) DUTIES.—Each center shall examine, analyze, issue reports and recommendations, gather, store, and disseminate information regarding the ethical issues and principles resulting from—

["(1) the conduct of biomedical and behavioral research;

["(2) the delivery of health care services and experimental therapy and procedures; and

["(3) the use of new technologies in the provision of health care.".

[(b) REPEAL.—Section 381 (42 U.S.C. 275) is repealed.

[SEC. 202. FETAL THERAPY AND RESEARCH.

[Section 498(c) (42 U.S.C. 298g) is amended to read as follows:

["(c)(1) Not later than 1 year after the date of enactment of this subsection, the Secretary shall appoint an Ethics Advisory Board that shall advise the Secretary and biomedical researchers regarding research on fetal therapy and on research involving human fetuses.

["(2) The Board shall consist of 15 members to be appointed as follows:

["(A) Seven members shall be appointed by the Secretary who shall be distinguished in biomedical or behavioral research. Of such members, four shall have had experience with research involving human fetuses, and three shall have had experience in research involving children.

["(B) Three members shall be appointed by the Secretary who shall be distinguished in the practice of medicine, or otherwise distinguished in the provision of health care. Of such members, one shall have expertise in obstetrics, and one shall have expertise in neonatology.

["(C) Four members shall be appointed by the Secretary who shall be distinguished in the fields of ethics, theology, and law.

["(D) One member shall be appointed by the Secretary who shall be representative of citizens with an interest in biomedical ethics but who shall possess no specific expertise in such.

["(3) The term of office of each member of the Board shall be 3 years, except that any such member appointed to fill a vacancy occurring prior to the expiration of the term for which such members predecessor was appointed shall be appointed for the remainder of such term. The terms of the members of the Board shall be staggered by the Secretary so as to establish a rotating membership.

[“(4)(A) Not later than 90 days after the date of enactment of this subsection, the Secretary shall issue a contract proposal, to which the National Academy of Sciences shall be invited to apply, for a grant or contract to examine the scientific, ethical, and funding issues surrounding the conduct of research on fetal therapy and involving human fetuses.

[“(B) As part of an examination conducted under subparagraph (A), the recipient shall review the regulations contained in section 46.208 of title 45, Code of Federal Regulations, and prepare and submit to the Secretary an analysis of the biomedical and ethical implications of exercising a waiver of the risk standard as contained in section 46.102(g) of title 45, Code of Federal Regulations. Not later than 18 months after the date of enactment of this subsection, the Secretary shall deliver a copy of such report to the Ethic Advisory Board, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate.

[“(5) During the 2-year period beginning on the date of enactment of this subsection, the Secretary may not grant (under section 46.211 of title 45, Code of Federal Regulations or any successor to such section) a modification or waiver for fetal research.”.

[TITLE III—NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

[SEC. 301. CENTERS FOR THE STUDY OF DEAFNESS AND OTHER COMMUNICATIVE DISORDERS.

[Subpart 10 of part C of title IV (42 U.S.C. 285j) is amended by adding at the end thereof the following new section:

[“SEC. 457A. CENTERS FOR THE STUDY OF DEAFNESS AND OTHER COMMUNICATIVE DISORDERS.

[“(a) GRANTS.—

[“(1) IN GENERAL.—The Director of the Institute may enter into cooperative agreements with, and make grants to, public or private nonprofit entities to pay all or part of the cost of planning, establishing, strengthening, or providing basic operating support for eight new or existing centers for disorders of hearing and communication diseases.

[“(2) POLICIES.—A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of the National Institutes of Health after consultation with the advisory council of the Institute.

[“(b) USE OF FUNDS.—Each center provided with funds, or otherwise assisted under this section, shall conduct—

[“(1) basic and clinical research into the cause diagnosis, early detection, prevention, control and treatment of, and rehabilitation from, disorders of hearing and other communication processes and complications resulting from such disorders;

["(2) training programs for physicians, scientists, and other health and allied health professionals;

["(3) information and continuing education programs for physicians and other health and allied health professionals who will provide care for patients with disorders of hearing or other communication processes; and

["(4) programs for the dissemination to the general public of information on the importance of prevention and early detection of disorders of hearing and other communication processes.

["(c) STIPENDS.—A center provided with funds or otherwise assisted subsection (a), may use funds provided under such subsection to provide stipends for health professionals enrolled in training programs described in subsection (b)(2).

["(d) DEMONSTRATION PROGRAMS.—Each center provided with funds or otherwise assisted subsection (a), may conduct demonstration programs—

["(1) to establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals at risk of developing disorders of hearing or other communication processes; and

["(2) to disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping.

["(e) DISTRIBUTION OF CENTERS.—The Director of the Institute shall, to the extent practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of the elderly, and of children affected by disorders of hearing or other communication processes.

[TITLE IV—NATIONAL INSTITUTE ON AGING

[SEC. 401. CENTERS OF GERIATRIC RESEARCH AND TRAINING.

[Subpart 5 of part C of title IV (42 U.S.C. 285e et seq.) is amended by adding at the end thereof the following new section:

["SEC. 445A. CENTERS OF GERIATRIC RESEARCH AND TRAINING.

["(a) GRANTS.—The Director of the Institute shall enter into cooperative agreements with, and make grants to, public and private nonprofit entities for the development or expansion of centers of excellence in geriatric research and training.

["(b) DUTIES OF CENTERS.—Each center developed or expanded under this section shall—

["(1) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director; and

["(2) conduct—

["(A) research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging;

[“(B) advanced training programs in current methods of diagnosis and treatment of such diseases, disorders, and complications;

[“(C) programs to develop individuals capable of conducting research concerning aging and concerning such diseases, disorders, and complications; and

[“(D) educational and training activities for students of the health professions to enhance the knowledge of such students in geriatrics.

[“(c) LIMITATIONS.—In making cooperative agreements and grants under this section for the development or expansion of centers, the Director of the Institute shall provide that such centers are—

[“(1) geographically distributed throughout the United States; and

[“(2) located at entities with proven research capabilities and emerging centers of excellence.”.

[TITLE V—NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH

[SEC. 501. NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH.

[Part E of title IV (42 U.S.C. 287 et seq.) is amended by adding at the end thereof the following new subpart:

[“Subpart 4—National Center for Medical Rehabilitation Research

[“SEC. 486A. PURPOSE OF THE CENTER.

[“The general purpose of the National Center for Medical Rehabilitation Research (hereafter in this subpart referred to as the ‘Center’) is the conduct and support of biomedical and related research and research training, the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, or other physiologic systems (hereafter in this subpart referred to as ‘medical rehabilitation’).

[“SEC. 486B. APPOINTMENT OF THE DIRECTOR.

[“The Director of the Center shall be appointed by the Secretary and shall report directly to the Director of the National Institutes of Health.

[“SEC. 486C. SPECIFIC AUTHORITIES.

[“In carrying out the purpose described in section 486A, the Director of the Center may—

[“(1) make grants and enter into cooperative agreements and contracts;

[“(2) provide for clinical trials with respect to medical rehabilitation;

[“(3) provide for research with respect to model systems of medical rehabilitation;

["(4) coordinate the activities of the Center with similar activities of other agencies of the Federal Government, including the other agencies of the National Institutes of Health, and with similar activities of other public entities and of private entities;

["(5) support multidisciplinary medical rehabilitation research conducted or supported by more than one such agency;

["(6) with the approval of the Director of the National Institutes of Health and the advisory council established under section 465F, appoint technical and scientific peer review groups in addition to any such groups appointed under section 402(b)(6); and

["(7) support medical rehabilitation research and training centers.

["SEC. 486D. RESEARCH PLAN.

["(a) Development.—After consultation with the Director of the Center, the advisory council established under section 486F, and the coordinating committee established under section 486E, the Director of the National Institutes of Health shall develop a comprehensive plan for the conduct and support of medical rehabilitation research.

["(b) Contents.—The plan shall identify priorities with respect to such research and shall provide for the coordination of such research conducted or supported by the agencies of the National Institutes of Health.

["(c) Revision.—The Director of National Institutes of Health shall (after consultation with the Director of the Center and with such advisory council and such coordinating committee) revise the plan as appropriate.

["SEC. 486E. COORDINATING COMMITTEE.

["(a) Establishment.—The Director of the National Institutes of Health shall establish a committee to be known as the Medical Rehabilitation Coordinating Committee (hereafter in this subpart referred to as the 'Coordinating Committee').

["(b) Composition.—The Coordinating Committee shall be composed of the directors of the National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Child Health and Human Development, the National Institute of Neurological and Communicative Disorders and Stroke, and of such other national research institutes as the Director of the National Institutes of Health determines to be appropriate.

["(c) Duties.—The Coordinating Committee shall make recommendations to the Director of the National Institutes of Health and the Director of the Center with respect to the content of the plan required in section 486D and with respect to the activities of the Center that are carried out in conjunction with other agencies of the National Institutes of Health.

["SEC. 486FG. ADVISORY COUNCIL.

["(a) Establishment.—The Director of the National Institutes of Health shall establish a council to be known as the Medical Rehabilitation Advisory Council (hereafter in this section referred to as the 'Advisory Council').

[“(b) DUTIES.—The Advisory Council shall advise, assist, consult with, and make recommendations to the Director of the National Institutes of Health and the Director of the Center on matters relating to the activities carried out by and through the Center and the policies respecting such activities, including recommendations with respect to the plan required in section 486D.

[“(c) MEMBERSHIP.—

[“(1) IN GENERAL.—The Director of the National Institutes of Health shall appoint to the Advisory Council 18 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, 12 shall be representatives of health and scientific disciplines with respect to medical rehabilitation and 6 shall be individuals representing the interests of individuals undergoing, or in need of, medical rehabilitation.

[“(2) EX OFFICIO MEMBERS.—The following officials shall serve as ex officio members of the Advisory Council:

[“(A) The Director of the National Institutes of Health.

[“(B) The Director of the Center.

[“(C) The Director of the National Institute on Aging.

[“(D) The Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

[“(E) The Director of the National Institute of Child Health and Human Development.

[“(F) The Director of the National Institute of Neurological and Communicative Disorders and Stroke.

[“(G) The Assistant Secretary for Special Education and Rehabilitative Services.

[“(H) The Assistant Secretary of Defense (Health Affairs).

[“(I) The Chief Medical Director of the Veterans' Administration.

[“(d) CHAIRPERSON.—The Director of the National Institutes of Health shall designate a chairperson from among the members of the Advisory Council.

[“(e) CONSTRUCTION.—Except as inconsistent with, or inapplicable to, this section, the provisions of section 406 shall apply to the advisory council established under this section in the same manner as such provisions apply to any advisory council established under section 406.”.

[TITLE VI—NATIONAL CENTER FOR NURSING RESEARCH

[SEC. 601. NATIONAL CENTER FOR NURSING RESEARCH.

[Section 484 (42 U.S.C. 287c–1) is amended to read as follows:

[“SEC. 484. SPECIFIC AUTHORITIES.

[“To carry out section 483, the Director of the Center may—

[“(1) provide research training and instruction and establish, in the Center and other nonprofit institutions, research traineeships and fellowships in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses;

[“(2) provide individuals receiving such training and instruction under paragraph (1) or such traineeships or fellowships with such stipends and allowances (including amounts for travel and subsistence and dependency allowances) as the Director determines necessary;

[“(3) make grants to nonprofit institutions to provide training and instruction and traineeships and fellowships under paragraph (1);

[“(4) enter into cooperative agreements with, and make grants to, public and private nonprofit entities to fund all or part of research and demonstration projects that may include projects for research concerning—

[“(A) innovative models of nursing care;

[“(B) problems relating to the national nursing shortage; and

[“(C) the quality of the nursing role with regard to patient care; and

[“(5) in consultation with the Advisory Council established under section 485, make grants for the acquisition, construction, or renovation of facilities.”.

[TITLE VII—NATIONAL CANCER INSTITUTE

[SEC. 701. PURPOSE.

[Section 410 (42 U.S.C. 285) is amended by inserting “and rehabilitation from” after “treatment of”.

[SEC. 702. SPECIAL AUTHORITIES OF THE DIRECTOR.

[Section 413(b) (42 U.S.C. 285a-2(b)) is amended—

[(1) in paragraph (5), by striking out “with the approval of” and inserting in lieu thereof “in consultation with”;

[(2) in paragraph (7), by inserting “and to conduct the technical and scientific peer review required by section 492(b)” before the semicolon;

[(3) in paragraph (9), by striking out “; and” and inserting in lieu thereof a semicolon;

[(4) by redesignating paragraph (10) as paragraph (11);

[(5) by inserting after paragraph (9) the following new paragraph:

[“(10) may publish or arrange for the publication of information regarding cancer research, prevention, biology and diagnosis, control, and treatment to cancer patients and their families, physicians, and other health professionals, oncologic investigators, and the general public without regard to section 501 of title 44, United States Code; and”; and

[(6) in paragraph (11) (as redesignated in paragraph (4)), by striking out “may” and inserting in lieu thereof “shall”.

[SEC. 703. NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS.

[Section 414(a)(1) (42 U.S.C. 285a-3(a)(1)) is amended by inserting "control," after "prevention,".

[TITLE VIII—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

[SEC. 801. INFORMATION AND EDUCATION.

[Paragraphs (1) and (2) of the second sentence of section 420 (42 U.S.C. 285b-2) is amended by striking out paragraphs (1) and (2) and inserting in lieu thereof the following: "the utilization of collaborative efforts with both the public and private sectors to—

[“(1) increase the awareness and knowledge of health care professionals and the public regarding the prevention of heart and blood vessel, lung, and blood diseases and the utilization of blood resources; and

[“(2) develop and disseminate to health professionals, patients and patient families, and the public of information designed to encourage adults and children to adopt healthful habits concerning the prevention of such diseases.".

[SEC. 802. RESOURCES PROGRAM.

[Section 421 (42 U.S.C. 285b-3) is amended—

[(1) in subsection (a)(1)(D), by inserting "and rehabilitation from" after "treatment of"; and

[(2) in subsection (b)—

[(A) by striking out "; and" in paragraph (3) and inserting in lieu thereof a semicolon;

[(B) by striking out the period at the end of paragraph (4) and inserting in lieu thereof "; and"; and

[(C) by adding at the end thereof the following new paragraph:

[“(5) shall, in consultation with the advisory council for the Institute, support appropriate programs for education and training (including continuing education and laboratory and clinical research training).".

[SEC. 803. NATIONAL RESEARCH AND DEMONSTRATION CENTERS.

[Section 422(a)(1) (42 U.S.C. 285b-4(a)(1)) is amended—

[(1) in subparagraph (A), by inserting "and rehabilitation" after "treatment"; and

[(2) in subparagraph (B), by inserting "and rehabilitation" after "treatment".

[SEC. 804. INTERAGENCY TECHNICAL COMMITTEE.

[Section 423 (42 U.S.C. 285b-5) is repealed.

[TITLE IX—NATIONAL INSTITUTES OF HEALTH

[SEC. 901. APPOINTMENT AND AUTHORITY OF THE DIRECTOR.

[Section 402(b)(6) (42 U.S.C. 282(b)(6)) is amended by inserting "and scientific program advisory committees" after "scientific peer review groups".

[TITLE X—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

[SEC. 1001. APPOINTMENT AND AUTHORITY OF THE DIRECTORS.

[(a) POWERS AND DUTIES OF DIRECTORS.—Section 405(b) (42 U.S.C. 284(b)) is amended—

[(1) in the matter preceding subparagraph (A) of paragraph (1)—

[(A) by striking out "the human diseases" and inserting in lieu thereof "human diseases";

[(B) by striking out "for which the national research institutes were established"; and

[(C) by inserting "and agency of the National Institutes of Health" after "each national research institute";

[(2) by adding at the end of paragraph (1) the following new sentence: "For purposes of Federal income, estate, and gift taxes, any gift accepted under subparagraph (H) shall be considered to be a gift or transfer to the United States."; and

[(3) in the matter preceding subparagraph (A) of paragraph (2), by inserting "and agency of the National Institutes of Health" after "research institute".

[(b) CARRYING OUT DUTIES.—Section 405(c) is amended—

[(1) in the matter preceding paragraph (1), by inserting "and agency of the National Institutes of Health" after "national research institute";

[(2) in paragraph (1), by inserting "or agency" after "institute";

[(3) in paragraph (2)—

[(A) by inserting "and agencies" after "institutes"; and

[(B) by inserting "or agency" after "institute"; and

[(4) by striking out paragraph (3) and inserting in lieu thereof the following new paragraph:

["(3) may—

["(A) with the approval of the advisory council for the institute or agency and the Director of the National Institutes of Health, establish technical and scientific peer review groups in addition to those established under section 402(b)(6); and

["(B) appoint the members of peer review groups established under subparagraph (A).".

[SEC. 1002. ADVISORY COUNCILS.

[(a) APPOINTMENT OF MEMBERS.—Section 406(b)(3)(A) (42 U.S.C. 284a(b)(3)(A)) is amended by striking out "public health and the" and inserting in lieu thereof "two individuals who are leaders in the fields of".

[(b) TERMINATION OF MEMBERSHIPS.—Section 406(h)(2)(A)(v) (42 U.S.C. 284a(h)(2)(A)(v)) is amended—

[(1) by inserting "shall be nonvoting members and" after "the Board"; and

[(2) by striking out "and the Assistant Secretary of Defense for Health Affairs" and inserting in lieu thereof "the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Energy Research of the Department of Energy".

[SEC. 1003. AUTHORIZATION OF APPROPRIATIONS.

[(a) IN GENERAL.—Paragraphs (1) and (2) of section 408(a) (42 U.S.C. 284c(a)) is amended to read as follows:

["(1)(A) For the National Cancer Institute (other than its programs under section 412), there are authorized to be appropriated $1,587,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991.

["(B) For the programs under section 412, there are authorized to be appropriated $84,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991.

["(2)(A) For the National Heart, Lung, and Blood Institute (other than its programs under section 419), there are authorized to be appropriated $1,001,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991. Of the amount appropriated under this subsection for such fiscal year, not less than 15 percent of such amount shall be reserved for programs respecting diseases of the lung and not less than 15 percent of such amount shall be reserved for programs respecting blood diseases and blood resources.

["(B) For the programs under section 419, there are authorized to be appropriated $101,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991.".

[(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall become effective on October 1, 1988.

[TITLE XI—NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

[SEC. 1101. ADVISORY BOARDS.

[Section 430 (42 U.S.C. 285c-4) is amended—

[(1) by striking out subsection (k); and

[(2) by redesignating subsection (l) as subsection (k).

[TITLE XII—NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

[SEC. 1201. NATIONAL ARTHRITIS AND MUSCULOSKELETAL DISEASES PROGRAMS.

[Section 436 (42 U.S.C. 285d-1) is amended to read as follows:

["SEC. 436. NATIONAL ARTHRITIS AND MUSCULOSKELETAL DISEASES PROGRAMS.

["(a) PLAN.—The Director of the Institute, with the advice of the Institute's advisory council, shall prepare and transmit to the Director of the National Institutes of Health a plan for a national arthritis, musculoskeletal and skin diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis, musculoskeletal and skin diseases. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of the National Institutes of Health.

["(b) ACTIVITIES.—Activities under the national arthritis, musculoskeletal and skin diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilities respecting arthritis, musculoskeletal and skin diseases, and shall, at least, provide for—

["(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis, musculoskeletal and skin diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis, musculoskeletal and skin diseases;

["(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation, and prevention of arthritis, musculoskeletal and skin diseases;

["(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures; and

["(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields.

["(c) ADMINISTRATION.—The Director of the Institute shall carry out the national arthritis, musculoskeletal and skin diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.".

[SEC. 1202. MULTIPURPOSE DISEASE CENTERS.

[Section 441(b)(2)(A) (42 U.S.C. 285d-6(b)(2)(A)) is amended by inserting "and rehabilitation from" after "treatment of".

[TITLE XIII—NATIONAL LIBRARY OF MEDICINE

[SEC. 1301. BOARD OF REGENTS.

[Section 466(a)(1)(A) (42 U.S.C. 286a(a)(1)(A)) is amended by striking out "ten members appointed by the Secretary" and inserting in lieu thereof "13 members appointed by the President".

[SEC. 1302. AUTHORIZATION OF APPROPRIATIONS.

[Section 469 (42 U.S.C. 286b) is amended by striking out the first sentence and inserting in lieu thereof the following new sentence: "For the purpose of grants and contracts under sections 472 through 476, there are authorized to be appropriated $14,000,000 for fiscal year 1989 and such sums as are necessary for each of the fiscal years 1990 and 1991.".

[SEC. 1303. GRANTS FOR THE DEVELOPMENT OF NEW EDUCATIONAL TECHNOLOGIES.

[Section 473 (42 U.S.C. 286b-4) is amended by adding at the end thereof the following new subsection:

["(c) The Secretary shall make grants to appropriate public or private nonprofit institutions for the purpose of carrying out projects in the research, development, and demonstration of new educational technologies. Such projects shall assist in the training of health professions students, and enhance and improve the research and teaching capabilities of health professionals. Funding may support projects including those concerning computer-assisted teaching at health professions and research institutions, the effective transfer of new information from research laboratories to appropriate clinical applications, the expansion of the laboratory and clinical uses of computer-stored research databases, and the testing of new technologies for training health care professionals in nontraditional settings.".

[SEC. 1304. GRANTS FOR BASIC RESOURCES OF MEDICAL LIBRARIES.

[(a) LIBRARY CONSTRUCTION AUTHORITY.—Section 474(a) (42 U.S.C. 286b-5(a)) is amended—

[(1) in paragraph (3), by striking out "and" after the semicolon;

[(2) in paragraph (4), by striking out the period at the end thereof and inserting in lieu thereof "; and"; and

[(3) by adding at the end thereof the following new paragraph:

["(5) the acquisition, construction, or renovation of facilities.".

[(b) REMOVAL OF GRANT CAP.—Section 474(b)(2) (42 U.S.C. 286b-5(b)(2)) is amended by striking out ", except that in no" and all that follows through "$500,000".

[SEC. 1305. GRANTS FOR ESTABLISHMENT OF REGIONAL MEDICAL LIBRARIES.

[Section 475(b) (42 U.S.C. 286b-6(b)) is amended—

[(1) in paragraph (4), by striking out "and" after the semicolon;

[(2) in paragraph (5), by striking out the period at the end thereof and inserting in lieu thereof "; and"; and

[(3) by adding at the end thereof the following new paragraph:

["(6) the acquisition, construction, or renovation of facilities.".

[TITLE XIV—AWARDS AND TRAINING

[SEC. 1401. NATIONAL RESEARCH SERVICE AWARDS.

[(a) Multidisciplinary Research.—Section 487(a) (42 U.S.C. 288(a)) is amended by adding at the end thereof the following new paragraph:

["(4) The Secretary, acting through the Director of the National Institutes of Health, shall assure that support is provided for multidisciplinary research training in disciplines not readily identified with existing categorical institutes.".

[(b) Authorization of Appropriations.—The first sentence of section 487(d) (42 U.S.C. 288(d)) to read as follows: "There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such awards $350,000,000 for fiscal year 1989 and such sums as are necessary for each of the fiscal years 1990 and 1991.".

[(c) Effective Date.—The amendment made by subsection (a) shall become effective on October 1, 1988.

[TITLE XV—GENERAL PROVISIONS

[SEC. 1501. PEER REVIEW REQUIREMENTS.

[Section 492 (42 U.S.C. 289a) is amended—

[(1) in subsection (a)(2)(A), by inserting "and congruent with changing review need," after "to the extent practical,"; and

[(2) in subsection (b), by inserting ", except as provided in section 413(b)(7)" before the period at the end thereof.

[TITLE XVI—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

[SEC. 1601. BIOMEDICAL RESEARCH.

[Part A of title III is amended by inserting after section 301 (42 U.S.C. 241) the following new section:

["SEC. 301A. BIOMEDICAL SCIENTIFIC SERVICE.

["(a) Establishment.—The Secretary is authorized to establish a Senior Biomedical Scientific Service (hereinafter in this section referred to as the 'Service').

["(b) Membership.—

["(1) Civil Service.—Individuals chosen to serve in the Service shall not be a part of the competitive service established under chapter 33 of subpart B of part I of title 5, United States Code.

[“(2) Appointment.—A person may be appointed to the Service by the Secretary based solely on that person's distinction and achievement in the fields of biomedical research or clinical research evaluation.

[“(c) Duties.—Members of the Service shall be assigned to duties that require expertise in biomedical research, behavioral research, or clinical research evaluation, and may also be assigned to supervise other scientists in carrying out the activities described in this subsection.

[“(d) Compensation.—Individuals selected to serve on the Service staff by the Secretary under subsection (b), shall be compensated at a rate not in excess of 110 percent of the annual rate of pay in effect for level I of the Executive Salary Schedule established in section 5512 of title 5, United States Code.

[“(e) Retirement.—For purposes of section 211, the continuous service in the Service of any person who commences such service on termination of service as a commissioned officer in the Public Health Service Corps may be treated as service as a commissioned officer in the Public Health Service Corps and shall not be considered as service that is subject to any other retirement system for officers and employees of the Federal government.”.]

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) Short Title.—This Act may be cited as the “National Research Institutes Reauthorization Act of 1988”.

(b) Table of Contents.—The table of contents is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. References to the Public Health Service Act.

TITLE I—BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

Sec. 101. Biomedical and behavioral research facilities.

TITLE II—BIOMEDICAL ETHICS

Sec. 201. Centers for biomedical ethics.
Sec. 202. Fetal therapy and research.

TITLE III—NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Sec. 301. National Institute on Deafness and Other Communication Disorders.

TITLE IV—NATIONAL INSTITUTE ON AGING

Sec. 401. Centers of geriatric research and training.

TITLE V—NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH

Sec. 501. National Center for Medical Rehabilitation Research.

TITLE VI—NATIONAL CENTER FOR NURSING RESEARCH

Sec. 601. National Center for Nursing Research.

TITLE VII—NATIONAL CANCER INSTITUTE

Sec. 701. Purpose.
Sec. 702. Special authorities of the Director.
Sec. 703. National cancer research and demonstration centers.

TITLE VIII—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Sec. 801. Information and education.
Sec. 802. Resources program.
Sec. 803. National research and demonstration centers.

Sec. 804. Interagency technical committee.

TITLE IX—NATIONAL INSTITUTES OF HEALTH

Sec. 901. Appointment and authority of the Director.

TITLE X—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

Sec. 1001. Appointment and authority of the directors.
Sec. 1002. Advisory councils.
Sec. 1003. Authorization of appropriations.

TITLE XI—NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Sec. 1101. Redesignation of National Institute of Diabetes and Digestive and Kidney Diseases.
Sec. 1102. Advisory boards.

TITLE XII—NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Sec. 1201. National arthritis and musculoskeletal disease programs.
Sec. 1202. Multipurpose disease centers.

TITLE XIII—NATIONAL LIBRARY OF MEDICINE

Sec. 1301. Board of regents.
Sec. 1302. Authorization of appropriations.
Sec. 1303. Grants for the development of new educational technologies.
Sec. 1304. Grants for basic resources of medical libraries.
Sec. 1305. Grants for establishment of regional medical libraries.

TITLE XIV—AWARDS AND TRAINING

Sec. 1401. National research service awards.

TITLE XV—GENERAL PROVISIONS

Sec. 1501. Peer review requirements.

TITLE XVI—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

Sec. 1601. Biomedical research.

SEC. 2. REFERENCES TO THE PUBLIC HEALTH SERVICE ACT.

Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act (42 U.S.C. 201 et seq.).

TITLE I—BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

SEC. 101. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

Title IV (42 U.S.C. 601 et seq.) is amended by adding at the end thereof the following new part:

“PART H—BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

“SEC. 499A. GRANTS FOR CONSTRUCTION.

“The Director of the National Institutes of Health, through the Director of Research Resources (hereinafter in this part referred to

as the 'Director'), is authorized to award grants to public and nonprofit private institutions to expand, remodel, renovate, or alter existing research facilities or construct new research facilities pursuant to this part. Applications for grants shall be evaluated on the basis of merit as provided in section 499H.

"SEC. 499B. TECHNICAL REVIEW BOARD ON BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

"(a) ESTABLISHMENT.—

"(1) IN GENERAL.—There is established in the Division of Research Resources of the National Institutes of Health a Technical Review Board on Biomedical and Behavioral Research Facilities (hereinafter referred to in this part as the 'Board') to advise the Director and the Advisory Council established pursuant to section 480 (hereinafter in this part referred to as the 'Advisory Council') on matters concerning the construction of facilities, and to conduct the peer review of applications received for this part.

"(2) MEMBERSHIP.—The Board shall be appointed by the Director, and consist of not fewer than—

"(A) 12 members appointed without regard to the civil service laws; and

"(B) an official of the National Science Foundation designated by the National Science Board.

"(3) FACTORS FOR APPOINTMENTS.—In selecting persons for appointment to the Board under paragraph (2), the Director shall consider factors such as—

"(A) experience in the planning, construction, financing, and administration of institutions engaged in the conduct of research in the biomedical or behavioral sciences;

"(B) familiarity with the need for biomedical or behavioral research facilities;

"(C) familiarity with the need for dentistry, nursing, pharmacy, and allied health professions research facilities; and

"(D) experience with emerging centers of excellence as defined in section 499C(d)(2).

"(b) DUTIES.—The Board shall—

"(1) advise and assist the Director and the Advisory Council in the preparation of general regulations and with respect to policy matters arising in the administration of this part;

"(2) make recommendations to the Director and the Advisory Council concerning—

"(A) merit review of applications for grants; and

"(B) the amount that should be granted to each applicant whose application, in its opinion, should be approved; and

"(3) prepare an annual report for the Advisory Council, which shall be available to the public, that—

"(A) describes the activities of the Board in the fiscal year for which the report is made;

"(B) describes and evaluates the progress made in such fiscal year in meeting the facilities needs for the biomedical research community;

"(C) summarizes and analyzes expenditures made by the Federal government for such activities;

"(D) reviews the approved but unfunded applications for grants; and

"(E) contains the recommendations of the Board for any changes in the implementation of this part.

"(c) TERMS.—

"(1) TERMS.—Each appointed member of the Board shall hold office for a term of 4 years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of such term.

"(2) STAGGERED TERMS.—Of the initial members appointed to the Board—

"(A) three shall hold office for a term of 3 years;
"(B) three shall hold office for a term of 2 years; and
"(C) three shall hold office for a term of 1 year;

as designated by the Director at the time of appointment.

"(3) REAPPOINTMENT.—No member shall be eligible for reappointment until a year has elapsed since the end of such member's preceding term.

"(d) COMPENSATION.—Members of the Board who are not officers or employees of the United States shall receive for each day the members are engaged in the performance of the functions of the Board compensation at the same rate received by members of other national advisory councils established under this title.

"(e) USE OF MEMBERS.—The Director is authorized to use the services of any member or members of the Board, and where appropriate, any member or members of any other national advisory council established pursuant to this title, in connection with matters related to the administration of this part, for such periods, in addition to conference periods, as the Director may determine. The Director shall make appropriate provision for consultation between and coordination of the work of the Board and the Advisory Council, with respect to matters bearing on the purposes and administration of this part.

"(f) ADMINISTRATION.—The administration of the Board's functions shall be the responsibility of the Director and shall be carried out in the same manner as the administration of the functions of the Advisory Council.

"(g) BOARD ACTIVITIES.—

"(1) IN GENERAL.—In carrying out its functions under this part, the Board may establish subcommittees, convene workshops and conferences, and collect data as the Board considers appropriate.

"(2) SUBCOMMITTEES.—Subcommittees formed under paragraph (1) may be composed of Board members and nonmember consultants with expertise in the particular area to be address by the subcommittees. The subcommittee may hold meetings as determined necessary to enable the subcommittee to carry out its activities.

"SEC. 499C. APPLICATION AND SELECTION FOR GRANTS.

"(a) SUBMISSION.—Applications for grants under this part shall be submitted no less frequently than annually to the Director by public and nonprofit private institutions.

"(b) AWARDING OF GRANTS.—A grant under this part may be awarded by the Director if—

"(1) the applicant institution is determined by the Director to be competent to engage in the type of research for which the proposed facility is to be constructed;

"(2) the applicant institution meets the eligibility conditions established by the Director;

"(3) the application contains or is supported by the reasonable assurances that—

"(A) for not less than 20 years after completion of construction, the facility will be used for the purposes of research for which it is to be constructed;

"(B) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility; and

"(C) sufficient funds will be available, when construction is completed, for effective use of the facility for the research for which it is being constructed; and

"(4) the proposed construction will expand the applicant's capacity for research, or is necessary to improve or maintain the quality of the applicant's research.

A grant under this part may be made only if the application therefor is recommended for approval by the Advisory Council.

"(c) ELIGIBILITY CONDITIONS.—Within such aggregate monetary limit as the Director may prescribe, applications that, solely by reason of the inability of the applicants to give the assurance required by subsection (b)(2), fail to meet the requirements for application set forth in this section, may be approved on condition that the applicants give the assurance required by such paragraph within a reasonable time and on such other reasonable terms and conditions as the Director may determine.

"(d) AWARDING GRANTS.—

"(1) IN GENERAL.—In acting on applications for grants under this part, the Director shall take into consideration—

"(A) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding capacity for biomedical or behavioral research and in improving the quality of such research;

"(B) the quality of research or training, or both, to be carried out in the facilities involved;

"(C) the need of the institution for such facilities in order to maintain or expand the institutions' research and training mission;

"(D) the congruence of the research activities to be carried out within the facility with the research and investigator manpower needs of the United States; and

"(E) the age and condition of existing research facilities and equipment.

"(2) INSTITUTIONS OF EMERGING EXCELLENCE.—

"(A) IN GENERAL.—In addition to paragraph (1), the Director shall consider other criteria for the awarding of

grants for the construction of research facilities to eligible institutions that demonstrate emerging excellence in biomedical or behavioral research.

"(B) Eligibility.—To be eligible for a grant under this paragraph, an institution shall—

"(i) have a plan for research or training advancement and the ability to carry out the plan; and

"(ii)(I) carry out research and research training programs that have a special relevance to a problem, concern, or unmet need of the United States;

"(II) have already demonstrated a commitment to enhancing and expanding their research productivity; or

"(III) have been productive in research or research development and training in settings where significant barriers to institutional development have been created by—

"(aa) the underrepresentation of minorities in health science careers;

"(bb) the health status deficit of a large segment of the population; or

"(cc) a regional deficit in health care technology, services, or research resources that can adversely affect health status in the future.

"SEC. 499D. AMOUNT OF GRANT; PAYMENTS.

"(a) Amount.—The amount of any grant awarded under this part shall be determined by the Director, except that such amount may not exceed—

"(1) 50 percent of the necessary cost of the construction of a proposed facility as determined by the Director; or

"(2) in the case of a multipurpose facility, 50 percent of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

"(b) Reservation of Amounts.—On approval of any application for a grant under this part, the Director shall reserve, from any appropriation available therefor, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with construction progress, as the Director may determine. The Director's reservation of any amount under this subsection may be amended by the Director, either on approval of an amendment of the application or on revision of the estimated cost of construction of the facility.

"(c) Exclusion of Certain Costs.—In determining the amount of any grant under this part, there shall be excluded from the cost of construction an amount equal to the sum of—

"(1) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to be financed in part by grant authorized under this part; and

"(2) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.

"(d) Waiver of Limitations.—The limitations imposed by subsection (a) may be waived at the discretion of the Director for institutions described in section 499C(d)(2).

"SEC. 499E. RECAPTURE OF PAYMENTS.

"If, within 20 years after the completion of construction for which a grant has been awarded under this part—

"(1) the applicant or other owner of the facility shall cease to be a public or nonprofit private institution; or

"(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so);

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by agreement of the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

"SEC. 499F. NONINTERFERENCE WITH ADMINISTRATION OF INSTITUTIONS.

"Except as otherwise specifically provided in this part, nothing contained in this part shall be construed as authorizing any department, agency, officer, or employee of the United States to exercise any direction, supervision, or control over, or impose any requirement or condition with respect to, the research conducted by, and the personnel or administration of, any institution.

"SEC. 499G. REGULATIONS.

"Within 6 months after the date of enactment of this part, the Director, after consultations with the Advisory Council, shall prescribe regulations regarding the eligibility of institutions for grants awarded under this part, and the terms and conditions of approving applications for such grants. The Director may prescribe such other regulations as the Director finds necessary to carry out this part.

"SEC. 499H. PEER REVIEW OF APPLICATIONS.

"(a) In General.—The Director shall require appropriate peer review of applications for grants under this part in accordance with section 492.

"(b) Manner of Review.—Review of grant applications shall be conducted in a manner consistent with the system of scientific peer review conducted by scholars with regard to applications for grants under this Act for biomedical and behavioral research.

"(c) Membership.—Members of the peer review group established by the Director under section 499B shall be individuals who by the virtue of their training or experience are eminently qualified to perform review functions, except that not more than one-fourth of the members of any peer review group shall be officers or employees of the United States.

"SEC. 499I. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to award grants and carry out this part $150,000,000 for fiscal year 1989 and such sums as necessary for each of the fiscal years 1990 and 1991. Sums appro-

priated pursuant to this section shall remain available until expended.

"SEC. 499J. DEFINITIONS.

"As used in this part:

"(1) Construction and Cost of Construction.—The terms 'construction' and 'cost of construction' include the construction of new buildings and the expansion, renovation, remodeling, and alteration of existing buildings, including architects' fees, but not including the cost of acquisition of land or offsite improvements.

"(2) Public or Nonprofit Private Institution.—The term 'public or nonprofit private institution' means an institution that conducts biomedical or behavioral research, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.".

TITLE II—BIOMEDICAL ETHICS

SEC. 201. CENTERS FOR BIOMEDICAL ETHICS.

Subpart 1 of part E of title IV (42 U.S.C. 287 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 481A. CENTERS FOR BIOMEDICAL ETHICS.

"(a) In General.—The Director of the Division of Research Resources shall enter into cooperative agreements and make grants to public and private nonprofit entities for the development or expansion of no less than five centers of excellence in biomedical and behavioral research ethics.

"(b) Duties.—Each center shall examine, analyze, issue reports and recommendations, gather, store, and disseminate information regarding the ethical issues and principles resulting from—

"(1) the conduct of biomedical and behavioral research;

"(2) the delivery of health care services and experimental therapy and procedures; and

"(3) the use of new technologies in the provision of health care.".

SEC. 202. FETAL THERAPY AND RESEARCH.

Section 498(c) (42 U.S.C. 298g) is amended to read as follows:

"(c)(1) Not later than 1 year after the date of enactment of this subsection, the Secretary shall appoint an Ethics Advisory Board that shall advise the Secretary and biomedical researchers regarding research on fetal therapy and on research involving human fetuses.

"(2) The Board shall consist of 15 members to be appointed as follows:

"(A) Seven members shall be appointed by the Secretary who shall be distinguished in biomedical or behavioral research. Of such members, four shall have had experience with research involving human fetuses, and three shall have had experience in research involving children.

"(B) Five members shall be appointed by the Secretary who shall be distinguished in the practice of medicine, or otherwise distinguished in the provision of health care. Of such members,

one shall have expertise in obstetrics, and one shall have expertise in neonatology.

"(C) Four members shall be appointed by the Secretary who shall be distinguished in the fields of ethics, theology, and law.

"(D) One member shall be appointed by the Secretary who shall be representative of citizens with an interest in biomedical ethics but who shall possess no specific expertise in such.

"(3) The term of office of each member of the Board shall be 3 years, except that any such member appointed to fill a vacancy occurring prior to the expiration of the term for which such members predecessor was appointed shall be appointed for the remainder of such term. The terms of the members of the Board shall be staggered by the Secretary so as to establish a rotating membership.

"(4)(A) Not later than 90 days after the date of enactment of this subsection, the Secretary shall issue a contract proposal, to which the National Academy of Sciences shall be invited to apply, for a grant or contract to examine the scientific, ethical, and funding issues surrounding the conduct of research on fetal therapy and involving human fetuses.

"(B) As part of an examination conducted under subparagraph (A), the recipient shall review the regulations contained in section 46.208 of title 45, Code of Federal Regulations, and prepare and submit to the Secretary an analysis of the biomedical and ethical implications of exercising a waiver of the risk standard as contained in section 46.102(g) of title 45, Code of Federal Regulations. Not later than 18 months after the date of enactment of this subsection, the Secretary shall deliver a copy of such report to the Ethic Advisory Board, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate.

"(5) During the 2-year period beginning on the date of enactment of this subsection, the Secretary may not grant (under section 46.211 of title 45, Code of Federal Regulations or any successor to such section) a modification or waiver for fetal research.".

TITLE III—NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

SEC. 301. NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS.

(a) ESTABLISHMENT AND TRANSFER OF FUNCTIONS.—Title IV is amended—

(1) in section 401(b)(1) (42 U.S.C. 281(b)(1))—

(A) by striking out "and Communicative" in subparagraph (J); and

(B) by adding at the end thereof the following new subparagraph:

"(M) The National Institute on Deafness and Other Communication Disorders.";

(2) in the heading for subpart 10 of part C, by striking out "and Communicative";

(3) in section 457 (42 U.S.C. 285j)—

(A) by striking out "and Communicative"; and

(B) by striking out "disorder, stroke," and all that follows and through the end thereof and inserting in lieu thereof "and disorder and stroke."; and

(4) in Part C (42 U.S.C. 285 et seq.), by adding at the end thereof the following new subpart:

"Subpart 13—National Institute on Deafness and Other Communication Disorders

"SEC. 464. PURPOSE OF THE INSTITUTE.

"The general purpose of the National Institute on Deafness and Other Communication Disorders (hereafter referred to in this subpart as the 'Institute') is the conduct and support of research and training, the dissemination of health information, and other programs with respect to disorders of hearing and other communication processes, including diseases affecting hearing, balance, voice, speech, taste, and smell.

"SEC. 464A. NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS PROGRAM.

"(a) ESTABLISHMENT.—

"(1) IN GENERAL.—The Director of the Institute, with the advice of the Institute's advisory council, shall establish a National Deafness and Other Communication Disorders Program (hereafter in this section referred to as the 'Program').

"(2) PREPARATION OF PLAN.—The Director of the Institute shall, with respect to the Program, prepare and transmit to the Director of the National Institutes of Health a plan to initiate, expand, intensify and coordinate the activities of the Institute respecting disorders of hearing, balance, voice, speech, taste, and smell.

"(3) CONTENTS OF PLAN.—The plan prepared under paragraph (1) shall include such comments and recommendations as the Director of the Institute determines appropriate.

"(4) REVISION OF PLAN.—The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Director of the National Institutes of Health.

"(b) ACTIVITIES.—Activities under the Program shall be coordinated with other national research institutes to the extent that such institutes have responsibilities respecting disorders of hearing or other communication processes and shall, at least, provide for—

"(1) investigation into the etiology, pathology, detection, treatment, and prevention of all forms of disorders of hearing and other communication processes, primarily through the support of basic research in such areas as epidemiology, immunology, physiology, genetics, anatomy, biochemistry, microbiology, bioengineering, pharmacology, otolaryngology, audiology, speech pathology, molecular biology and the neurosciences, and any other scientific disciplines which can contribute important knowledge to the understanding and elimination of disorders of hearing and other communication processes;

"(2) research into the evaluation of techniques, drugs, and devices (including hearing aids, implanted auditory prosthetic devices and artificial speech aids for protection as well as assistance for these patients used in diagnosis, treatment, rehabilitation and prevention of disorders of hearing and other communication processes;

"(3) research into early detection and diagnosis of hearing loss and speech disturbances (including stuttering in children) and research into preventing the effects of such disorders on learning and learning disabilities with extension of programs for appropriate referral and rehabilitation;

"(4) research into the detection, treatment, and prevention of disorders of hearing and other communication processes in the growing elderly population with extension of rehabilitative programs to ensure continued effective communication skills in such population; and

"(5) research to refine the basic understanding of the effects of environmental agents that influence hearing or other communication processes.

"SEC. 464B. DATA SYSTEM AND INFORMATION CLEARINGHOUSE.

"(a) Data System.—The Director of the Institute shall establish a National Deafness and Other Communication Disorders Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with disorders of hearing or other communication processes, including where possible, data involving general populations for the purpose of identifying individuals at risk of developing such disorders.

"(b) Information Clearinghouse.—The Director of the Institute shall establish a National Deafness and Other Communication Disorders Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of disorders of hearing and other communication processes by health professionals, patients, industry, and the public.

"SEC. 466C. MULTIPURPOSE DEAFNESS AND OTHER COMMUNICATION DISORDERS CENTER.

"(a) Development.—

"(1) In general.—The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including care required for research) of new and existing centers for studies of disorders of hearing and other communication processes.

"(2) Definition.—For purposes of this section, the term 'modernization' means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

"(b) Requirements of Centers.—Each center assisted under this section shall—

"(1) use the facilities of a single institution or a consortium of cooperating institutions; and

"(2) meet such qualifications as may be prescribed by the Secretary.

"(c) ACTIVITIES OF CENTERS.—Each center assisted under this section shall conduct—

"(1) basic and clinical research into the cause diagnosis, early detection, prevention, control and treatment of disorders of hearing and other communication processes and complications resulting from such disorders, including research into rehabilitative aids, implantable biomaterials, auditory speech processors, speech production devices, and other otolaryngologic procedures;

"(2) training programs for physicians, scientists, and other health and allied health professionals;

"(3) information and continuing education programs for physicians and other health and allied health professionals who will provide care for patients with disorders of hearing or other communication processes; and

"(4) programs for the dissemination to the general public of information—

"(A) on the importance of early detection of disorders of hearing and other communication processes, of seeking prompt treatment, rehabilitation, and of the following an appropriate regimen; and

"(B) on the importance of avoiding exposure to noise and other environmental toxic agents that may affect disorders of hearing or other communication processes.

"(d) STIPENDS.—A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in subsection (c)(2).

"(e) PROGRAMS.—Each center assisted under this section may conduct programs—

"(1) to establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals at risk of developing disorders of hearing or other communication processes; and

"(2) to disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping.

"(f) DISTRIBUTION OF CENTERS.—

"(1) GEOGRAPHICAL LOCATION.—The Director of the Institute shall, to the extent practicable, provide for an equitable geographical distribution of centers assisted under this section.

"(2) CHILDREN AND ELDERLY INDIVIDUALS.—The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of the elderly, and of children (particularly with respect to their education and training), affected by disorders of hearing or other communication processes.

"(g) PERIOD OF SUPPORT.—

"(1) IN GENERAL.—Support of a center under this section may be for a period not to exceed 7 years.

"(2) EXTENTION OF PERIOD.—The period referred to in paragraph (1) may be extended by the Director of the Institute for one or more additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director, with the advice of the Institute's advisory council, if

such group has recommended to the Director that such period should be extended.

"SEC. 464D. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as are determined necessary by the Secretary.".

(b) TRANSITIONAL AND SAVINGS PROVISIONS.—

(1) TRANSFER OF PERSONNEL, ASSETS, AND LIABILITIES.—Personnel employed by the National Institutes of Health in connection with the functions vested, under the amendments made by subsection (a), in the Director of the National Institute on Deafness and Other Communication Disorders, and assets, property, contracts, liabilities, records, unexpended balances of appropriations, authorizations, allocations, and other funds of the National Institutes of Health, arising from or employed, held, used, available to, or to be made available, in connection with such functions shall be transferred to the Director for appropriate allocation. Unexpended funds transferred under this subsection shall be used only for the purposes for which the funds were originally authorized and appropriated.

(2) SAVINGS PROVISIONS.—With respect to functions vested, under the amendments made by subsection (a), in the Director of the National Institute on Deafness and Other Communication Disorders, all orders, rules, regulations, grants, contracts, certificates, licenses, privileges, and other determinations, actions, or official documents, that have been issued, made, granted, or allowed to become effective, and that are effective on the date of the enactment of this Act, shall continue in effect according to their terms unless changed pursuant to law.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect October 1, 1988, or on the date of the enactment of this Act, whichever occurs later.

TITLE IV—NATIONAL INSTITUTE ON AGING

SEC. 401. CENTERS OF GERIATRIC RESEARCH AND TRAINING.

Subpart 5 of part C of title IV (42 U.S.C. 285e et seq.) is amended by adding at the end thereof the following new section:

"SEC. 445A. CENTERS OF GERIATRIC RESEARCH AND TRAINING.

"(a) GRANTS.—The Director of the Institute shall enter into cooperative agreements with, and make grants to, public and private nonprofit entities for the development or expansion of centers of excellence in geriatric research and training.

"(b) DUTIES OF CENTERS.—Each center developed or expanded under this section shall—

"(1) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director; and

"(2) conduct—

"(A) research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging; and

"(B) programs to develop individuals capable of conducting research concerning aging and concerning such diseases, disorders, and complications.

"(c) LIMITATIONS.—In making cooperative agreements and grants under this section for the development or expansion of centers, the Director of the Institute shall provide that such centers are—

"(1) geographically distributed throughout the United States; and

"(2) located at entities with proven research capabilities and emerging centers of excellence.".

TITLE V—NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH

SEC. 501. NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH.

Part E of title IV (42 U.S.C. 287 et seq.) is amended by adding at the end thereof the following new subpart:

"Subpart 4—National Center for Medical Rehabilitation Research

"SEC. 486A. PURPOSE OF THE CENTER.

"The general purpose of the National Center for Medical Rehabilitation Research (hereafter in this subpart referred to as the 'Center') is the conduct and support of biomedical and related research and research training, the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, or other physiologic systems (hereafter in this subpart referred to as 'medical rehabilitation').

"SEC. 486B. APPOINTMENT OF THE DIRECTOR.

"The Director of the Center shall be appointed by the Secretary and shall report directly to the Director of the National Institutes of Health.

"SEC. 486C. SPECIFIC AUTHORITIES.

"In carrying out the purpose described in section 486A, the Director of the Center may—

"(1) make grants and enter into cooperative agreements and contracts;

"(2) provide for clinical trials with respect to medical rehabilitation;

"(3) provide for research with respect to model systems of medical rehabilitation;

"(4) coordinate the activities of the Center with similar activities of other agencies of the Federal Government, including the other agencies of the National Institutes of Health, and with similar activities of other public entities and of private entities;

“(5) support multidisciplinary medical rehabilitation research conducted or supported by more than one such agency;

“(6) with the approval of the Director of the National Institutes of Health and the advisory council established under section 465F, appoint technical and scientific peer review groups in addition to any such groups appointed under section 402(b)(6); and

“(7) support medical rehabilitation research and training centers.

“SEC. 486D. RESEARCH PLAN.

“(a) Development.—After consultation with the Director of the Center, the advisory council established under section 486F, and the coordinating committee established under section 486E, the Director of the National Institutes of Health shall develop a comprehensive plan for the conduct and support of medical rehabilitation research.

“(b) Contents.—The plan shall identify priorities with respect to such research and shall provide for the coordination of such research conducted or supported by the agencies of the National Institutes of Health.

“(c) Revision.— The Director of National Institutes of Health shall (after consultation with the Director of the Center and with such advisory council and such coordinating committee) revise the plan as appropriate.

“SEC. 486E. COORDINATING COMMITTEE.

“(a) Establishment.—The Director of the National Institutes of Health shall establish a committee to be known as the Medical Rehabilitation Coordinating Committee (hereafter in this subpart referred to as the ‘Coordinating Committee’).

“(b) Composition.—The Coordinating Committee shall be composed of the directors of the National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Child Health and Human Development, the National Institute of Neurological and Communicative Disorders and Stroke, and of such other national research institutes as the Director of the National Institutes of Health determines to be appropriate.

“(c) Duties.—The Coordinating Committee shall make recommendations to the Director of National Institutes of Health and the Director of the Center with respect to the content of the plan required in section 486D and with respect to the activities of the Center that are carried out in conjunction with other agencies of the National Institutes of Health.

“SEC. 486FG. ADVISORY COUNCIL.

“(a) Establishment.—The Director of the National Institutes of Health shall establish a council to be known as the Medical Rehabilitation Advisory Council (hereafter in this section referred to as the ‘Advisory Council’.)

“(b) Duties.—The Advisory Council shall advise, assist, consult with, and make recommendations to the Director of the National Institutes of Health and the Director of the Center on matters relating to the activities carried out by and through the Center and the

policies respecting such activities, including recommendations with respect to the plan required in section 486D.

"(c) MEMBERSHIP.—

"(1) IN GENERAL.—The Director of the National Institutes of Health shall appoint to the Advisory Council 18 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, 12 shall be representatives of health and scientific disciplines with respect to medical rehabilitation and 6 shall be individuals representing the interests of individuals undergoing, or in need of, medical rehabilitation.

"(2) EX OFFICIO MEMBERS.—The following officials shall serve as ex officio members of the Advisory Council:

"(A) The Director of the National Institutes of Health.

"(B) The Director of the Center.

"(C) The Director of the National Institute on Aging.

"(D) The Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

"(E) The Director of the National Institute of Child Health and Human Development.

"(F) The Director of the National Institute of Neurological and Communicative Disorders and Stroke.

"(G) The Assistant Secretary for Special Education and Rehabilitative Services.

"(H) The Assistant Secretary of Defense (Health Affairs).

"(I) The Chief Medical Director of the Veterans' Administration.

"(d) CHAIRPERSON.—The Director of the National Institutes of Health shall designate a chairperson from among the members of the Advisory Council.

"(e) CONSTRUCTION.—Except as inconsistent with, or inapplicable to, this section, the provisions of section 406 shall apply to the advisory council established under this section in the same manner as such provisions apply to any advisory council established under section 406.".

TITLE VI—NATIONAL CENTER FOR NURSING RESEARCH

SEC. 601. NATIONAL CENTER FOR NURSING RESEARCH.

Section 484 (42 U.S.C. 287c-1) is amended to read as follows:

"SEC. 484. SPECIFIC AUTHORITIES.

"To carry out section 483, the Director of the Center may—

"(1) provide research training and instruction and establish, in the Center and other nonprofit institutions, research traineeships and fellowships in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses;

"(2) provide individuals receiving such training and instruction under paragraph (1) or such traineeships or fellowships with such stipends and allowances (including amounts for

travel and subsistence and dependency allowances) as the Director determines necessary;

"(3) make grants to nonprofit institutions to provide training and instruction and traineeships and fellowships under paragraph (1);

"(4) enter into cooperative agreements with, and make grants to, public and private nonprofit entities to fund all or part of research and demonstration projects that may include projects for research concerning—

"(A) innovative models of nursing care;

"(B) problems relating to the national nursing shortage; and

"(C) the quality of the nursing role with regard to patient care; and

"(5) in consultation with the Advisory Council established under section 485, make grants for the acquisition, construction, or renovation of facilities.".

TITLE VII—NATIONAL CANCER INSTITUTE

SEC. 701. PURPOSE.

Section 410 (42 U.S.C. 285) is amended by inserting "and rehabilitation from" after "treatment of".

SEC. 702. SPECIAL AUTHORITIES OF THE DIRECTOR.

Section 413(b) (42 U.S.C. 285a-2(b)) is amended—

(1) in paragraph (5), by striking out "with the approval of" and inserting in lieu thereof "in consultation with";

(2) in paragraph (7), by inserting "and to conduct the technical and scientific peer review required by section 492(b)" before the semicolon;

(3) in paragraph (9), by striking out "; and" and inserting in lieu thereof a semicolon;

(4) by redesignating paragraph (10) as paragraph (11);

(5) by inserting after paragraph (9) the following new paragraph:

"(10) may publish or arrange for the publication of information regarding cancer research, prevention, biology and diagnosis, control, and treatment to cancer patients and their families, physicians, and other health professionals, oncologic investigators, and the general public without regard to section 501 of title 44, United States Code; and"; and

(6) in paragraph (11) (as redesignated in paragraph (4)), by striking out "may" and inserting in lieu thereof "shall".

SEC. 703. NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS.

Section 414(a)(1) (42 U.S.C. 285a-3(a)(1)) is amended by inserting "control," after "prevention,".

TITLE VIII—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

SEC. 801. INFORMATION AND EDUCATION.

Paragraphs (1) and (2) of the second sentence of section 420 (42 U.S.C. 285b-2) is amended by striking out paragraphs (1) and (2) and inserting in lieu thereof the following: "the utilization of collaborative efforts with both the public and private sectors to—

"(1) increase the awareness and knowledge of health care professionals and the public regarding the prevention of heart and blood vessel, lung, and blood diseases and the utilization of blood resources; and

"(2) develop and disseminate to health professionals, patients and patient families, and the public information designed to encourage adults and children to adopt healthful habits concerning the prevention of such diseases.".

SEC. 802. RESOURCES PROGRAM.

Section 421 (42 U.S.C. 285b-3) is amended—

(1) in subsection (a)(1)(D), by inserting "and rehabilitation from" after "treatment of"; and

(2) in subsection (b)—

(A) by striking out "; and" in paragraph (3) and inserting in lieu thereof a semicolon;

(B) by striking out the period at the end of paragraph (4) and inserting in lieu thereof "; and"; and

(C) by adding at the end thereof the following new paragraph:

"(5) shall, in consultation with the advisory council for the Institute, support appropriate programs for education and training (including continuing education and laboratory and clinical research training).".

SEC. 803. NATIONAL RESEARCH AND DEMONSTRATION CENTERS.

Section 422(a)(1) (42 U.S.C. 285b-4(a)(1)) is amended—

(1) in subparagraph (A), by inserting "and rehabilitation" after "treatment"; and

(2) in subparagraph (B), by inserting "and rehabilitation" after "treatment".

SEC. 804. INTERAGENCY TECHNICAL COMMITTEE.

Section 423 (42 U.S.C. 285b-5) is repealed.

TITLE IX—NATIONAL INSTITUTES OF HEALTH

SEC. 901. APPOINTMENT AND AUTHORITY OF THE DIRECTOR.

Section 402(b)(6) (42 U.S.C. 282(b)(6)) is amended by inserting "and scientific program advisory committees" after "scientific peer review groups".

TITLE X—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

SEC. 1001. APPOINTMENT AND AUTHORITY OF THE DIRECTORS.

(a) POWERS AND DUTIES OF DIRECTORS.—Section 405(b) (42 U.S.C. 284(b)) is amended—

(1) in the matter preceding subparagraph (A) of paragraph (1)—

(A) by striking out "the human diseases" and inserting in lieu thereof "human diseases";

(B) by striking out "for which the national research institutes were established"; and

(C) by inserting "and agency of the National Institutes of Health" after "each national research institute";

(2) by adding at the end of paragraph (1) the following new sentence: "For purposes of Federal income, estate, and gift taxes, any gift accepted under subparagraph (H) shall be considered to be a gift or transfer to the United States."; and

(3) in the matter preceding subparagraph (A) of paragraph (2), by inserting "and agency of the National Institutes of Health" after "research institute".

(b) CARRYING OUT DUTIES.—Section 405(c) is amended—

(1) in the matter preceding paragraph (1), by inserting "and agency of the National Institutes of Health" after "national research institute";

(2) in paragraph (1), by inserting "or agency" after "institute";

(3) in paragraph (2)—

(A) by inserting "and agencies" after "institutes"; and

(B) by inserting "or agency" after "institute"; and

(4) by striking out paragraph (3) and inserting in lieu thereof the following new paragraph:

"(3) may—

"(A) with the approval of the advisory council for the institute or agency and the Director of the National Institutes of Health, establish technical and scientific peer review groups in addition to those established under section 402(b)(6); and

"(B) appoint the members of peer review groups established under subparagraph (A).".

SEC. 1002. ADVISORY COUNCILS.

(a) APPOINTMENT OF MEMBERS.—Section 406(b)(3)(A) (42 U.S.C. 284a(b)(3)(A)) is amended by inserting "two individuals who are leaders in the fields of" after "(including".

(b) TERMINATION OF MEMBERSHIPS.—Section 406(h)(2)(A)(v) (42 U.S.C. 284a(h)(2)(A)(v)) is amended—

(1) by inserting "shall be nonvoting members and" after "the Board"; and

(2) by striking out "and the Assistant Secretary of Defense for Health Affairs" and inserting in lieu thereof "the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Energy Research of the Department of Energy".

SEC. 1003. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Paragraphs (1) and (2) of section 408(a) (42 U.S.C. 284c(a)) is amended to read as follows:

"(1)(A) For the National Cancer Institute (other than its programs under section 412), there are authorized to be appropriated $1,587,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991.

"(B) For the programs under section 412, there are authorized to be appropriated $84,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991.

"(2)(A) For the National Heart, Lung, and Blood Institute (other than its programs under section 419), there are authorized to be appropriated $1,001,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991. Of the amount appropriated under this subsection for such fiscal year, not less than 15 percent of such amount shall be reserved for programs respecting diseases of the lung and not less than 15 percent of such amount shall be reserved for programs respecting blood diseases and blood resources.

"(B) For the programs under section 419, there are authorized to be appropriated $101,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall become effective on October 1, 1988.

TITLE XI—NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SEC. 1101. REDESIGNATION OF NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES.

Title IV (42 U.S.C. 601 et seq.) is amended by striking out "National Institute of Diabetes and Digestive and Kidney Diseases" each place it appears in sections 401(b)(1)(C), 426, and 430(b)(2)(A)(i) (42 U.S.C. 281(b)(1)(C), 285c, and 285c-4(b)(2)(A)(i)) and the heading for subpart 3 of part C (42 U.S.C. prec. 285c) and inserting in lieu thereof "National Institute of Diabetes, Digestive and Kidney Diseases, and Endocrinology".

SEC. 1102. ADVISORY BOARDS.

Section 430 (42 U.S.C. 285c-4) is amended—

(1) by striking out subsection (k); and

(2) by redesignating subsection (l) as subsection (k).

TITLE XII—NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

SEC. 1201. NATIONAL ARTHRITIS AND MUSCULOSKELETAL DISEASES PROGRAMS.

Section 436 (42 U.S.C. 285d-1) is amended to read as follows:

"SEC. 436. NATIONAL ARTHRITIS AND MUSCULOSKELETAL DISEASES PROGRAMS.

"(a) PLAN.—The Director of the Institute, with the advice of the Institute's advisory council, shall prepare and transmit to the Director of the National Institutes of Health a plan for a national arthritis, musculoskeletal and skin diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis, musculoskeletal and skin diseases. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of the National Institutes of Health.

"(b) ACTIVITIES.—Activities under the national arthritis, musculoskeletal and skin diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilities respecting arthritis, musculoskeletal and skin diseases, and shall, at least, provide for—

"(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis, musculoskeletal and skin diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis, musculoskeletal and skin diseases;

"(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation, and prevention of arthritis, musculoskeletal and skin diseases;

"(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures; and

"(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields.

"(c) ADMINISTRATION.—The Director of the Institute shall carry out the national arthritis, musculoskeletal and skin diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.".

SEC. 1202. MULTIPURPOSE DISEASE CENTERS.

Section 441(b)(2)(A) (42 U.S.C. 285d-6(b)(2)(A)) is amended by inserting "and rehabilitation from" after "treatment of".

TITLE XIII—NATIONAL LIBRARY OF MEDICINE

SEC. 1301. BOARD OF REGENTS.

Section 466(a)(1)(A) (42 U.S.C. 286a(a)(1)(A)) is amended by striking out "ten members appointed by the Secretary" and inserting in lieu thereof "13 members appointed by the President".

SEC. 1302. AUTHORIZATION OF APPROPRIATIONS.

Section 469 (42 U.S.C. 286b) is amended by striking out the first sentence and inserting in lieu thereof the following new sentence: "For the purpose of grants and contracts under sections 472 through 476, there are authorized to be appropriated $14,000,000 for fiscal year 1989 and such sums as are necessary for each of the fiscal years 1990 and 1991.".

SEC. 1303. GRANTS FOR THE DEVELOPMENT OF NEW EDUCATIONAL TECHNOLOGIES.

Section 473 (42 U.S.C. 286b–4) is amended by adding at the end thereof the following new subsection:

"(c) The Secretary shall make grants to appropriate public or private nonprofit institutions for the purpose of carrying out projects in the research, development, and demonstration of new educational technologies. Such projects shall assist in the training of health professions students, and enhance and improve the research and teaching capabilities of health professionals. Funding may support projects including those concerning computer-assisted teaching and testing of clinical competence at health professions and research institutions, the effective transfer of new information from research laboratories to appropriate clinical applications, the expansion of the laboratory and clinical uses of computer-stored research databases, and the testing of new technologies for training health care professionals in non-traditional settings.".

SEC. 1304. GRANTS FOR BASIC RESOURCES OF MEDICAL LIBRARIES.

(a) LIBRARY CONSTRUCTION AUTHORITY.—Section 474(a) (42 U.S.C. 286b–5(a)) is amended—

(1) in paragraph (3), by striking out "and" after the semicolon;

(2) in paragraph (4), by striking out the period at the end thereof and inserting in lieu thereof "; and"; and

(3) by adding at the end thereof the following new paragraph:

"(5) the acquisition, construction, or renovation of facilities.".

(b) REMOVAL OF GRANT CAP.—Section 474(b)(2) (42 U.S.C. 286b–5(b)(2)) is amended by striking out ", except that in no" and all that follows through "$500,000".

SEC. 1305. GRANTS FOR ESTABLISHMENT OF REGIONAL MEDICAL LIBRARIES.

Section 475(b) (42 U.S.C. 286b–6(b)) is amended—

(1) in paragraph (4), by striking out "and" after the semicolon;

(2) in paragraph (5), by striking out the period at the end thereof and inserting in lieu thereof "; and"; and

(3) by adding at the end thereof the following new paragraph:

"(6) the acquisition, construction, or renovation of facilities.".

TITLE XIV—AWARDS AND TRAINING

SEC. 1401. NATIONAL RESEARCH SERVICE AWARDS.

(a) MULTIDISCIPLINARY RESEARCH.—Section 487(a) (42 U.S.C. 288(a)) is amended by adding at the end thereof the following new paragraph:

"(4) The Secretary, acting through the Director of the National Institutes of Health, shall assure that support is provided for multidisciplinary research training in disciplines not readily identified with existing categorical institutes.".

(b) AUTHORIZATION OF APPROPRIATIONS.—The first sentence of section 487(d) (42 U.S.C. 288(d)) to read as follows: "There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such awards $350,000,000 for fiscal year 1989 and such sums as are necessary for each of the fiscal years 1990 and 1991.".

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall become effective on October 1, 1988.

TITLE XV—GENERAL PROVISIONS

SEC. 1501. PEER REVIEW REQUIREMENTS.

Section 492 (42 U.S.C. 289a) is amended—

(1) in subsection (a)(2)(A), by inserting "and congruent with changing review need," after "to the extent practical,"; and

(2) in subsection (b), by inserting ", except as provided in section 413(b)(7)" before the period at the end thereof.

TITLE XVI—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

SEC. 1601. BIOMEDICAL RESEARCH.

Part A of title III is amended by inserting after section 301 (42 U.S.C. 241) the following new section:

"SEC. 301A. BIOMEDICAL SCIENTIFIC SERVICE.

"(a) ESTABLISHMENT.—The Secretary is authorized to establish a Senior Biomedical Scientific Service (hereinafter in this section referred to as the 'Service').

"(b) MEMBERSHIP.—

"(1) CIVIL SERVICE.—Individuals chosen to serve in the Service shall not be a part of the competitive service established under chapter 33 of subpart B of part I of title 5, United States Code.

"(2) APPOINTMENT.—A person may be appointed to the Service by the Secretary based solely on that person's distinction and achievement in the fields of biomedical research or clinical research evaluation.

"(c) DUTIES.—Members of the Service shall be assigned to duties that require expertise in biomedical research, behavioral research, or clinical research evaluation, and may also be assigned to supervise other scientists in carrying out the activities described in this subsection.

"(d) COMPENSATION.—Individuals selected to serve on the Service staff by the Secretary under subsection (b), shall be compensated at a rate not in excess of 110 percent of the annual rate of pay in effect for level I of the Executive Salary Schedule established in section 5512 of title 5, United States Code.

"(e) RETIREMENT.—For purposes of section 211, the continuous service in the Service of any person who commences such service on termination of service as a commissioned officer in the Public Health Service Corps may be treated as service as a commissioned officer in the Public Health Service Corps and shall not be considered as service that is subject to any other retirement system for officers and employees of the Federal government.".

COMMITTEE VIEWS

The Committee finds that the performance of the National Institutes of Health Operating under the terms of the Health Research Extension Act of 1985 was exemplary. Outstanding progress has been made in research and training. Much of this progress has been achieved under trying circumstances. The Administration has sought to restrict funds available to the NIH with inadequate budget requests and by ploys such as "forward funding". In fact, the Committee is greatly concerned by the continual need for NIH to negotiate grant awards downward from study section recommended levels, a practice which will, in the long term, slow down research progress and delay, if not prevent, needed clinical breakthroughs. Nevertheless, the NIH has managed its mission extremely well with a minimum of disruption to researchers in the field despite such Administration initiatives. Furthermore, the NIH has been able to attend to its broad responsibilities while responding to the AIDS crisis. It is with the foregoing in mind that the Committee makes its recommendations. The intent of this reauthorizing legislation is not to alter NIH activities, but to enhance them by expanding their scope and depth.

FACILITIES CONSTRUCTION AUTHORITY

The Committee further finds that the most ominous threat to medical research progress is the growing deficit in satisfactory research space. The Committee is alarmed by the increasing number of reports that research progress is being curtailed for lack of new research space or for lack of properly maintained or renovated research space. The Committee has heard many disturbing reports of department chairs that cannot be filled, difficulties in recruiting other faculty and graduate students, inability to house sophisticated equipment and computers, difficulties in meeting strict environmental and safety standards, and problems complying with humane standards for animal use that are all caused by insufficient or unsatisfactory research space.

The Committee is not alone in Congress in its concern over this serious problem. In 1985, the Senate Appropriations Committee (Report No. 98-544) stated:

> The Committee finds increasing evidence that the Nation's health facilities are slowly deteriorating and the great need for a new Federal construction program to replace outmoded facilities, relieve overcrowding, and accommodate changing research requirements must be addressed.

In 1987, the Senate Appropriations Committee (Report No. 100-189) stated:

> The Committee believes research is hampered by aging and obsolete research facilities and instrumentation. However, the question of Federal support for the construction of health sciences facilities is one of the most complicated biomedical research support issues facing the Congress. This question involves a variety of subquestions including how one measures the need for such assistance, what share of this need the Federal Government should assume, what mechanisms could best be used to channel Federal aid to contruction and how funds, if available, should be allocated among competing institutions. These questions have been further complicated by recent studies by the National Science Foundation which surveyed the research community and found a large amount of construction in the life and medical sciences currently underway—mostly financed from non-Federal sources. To this end, the Committee has provided adequate funding within the Office of the Director to convene a group of no more than 10 consultants to recommend the design, program balance, and administration of an initial pilot research facilities construction program at NIH.

Several bills have been introduced to address the facilities problem at universities. Two of the more notable are H.R. 2823, the "University Research Facilities Act of 1985", introduced by Representative Don Fuqua and not acted on, and H.R. 1905, the "University Research Facilities Act of 1987", introduced by Representative Robert A. Roe as part of the reauthorization bill for the National Science Foundation which is pending. These bills do not address health science needs specifically.

The estimates of funding, necessary to rectify the current situation are staggering, ranging from $5–20 billion over a 10 to 20 year period. A recent study by the National Science Foundation, "Science and Engineering Facilities at Doctorate-Granting Institutions", September 1986, reported on two quick response surveys covering nine fields of science and engineering at 165 doctorate-granting institutions. Ninety-five percent of the research administrators said that they had less space than they needed. Approximately one-third of the life science and medical school research administrators and deans ranked facilities as the major problem facing research in the next five years. Perhaps most troubling, the study stated, "Over 80 percent of the reseaarch administrators said that facilities needs limited the number and type of projects that could be carried out on their campuses and that it had been necessary to divert funds from other research areas to maintain and/or repair facilities."

The NSF survey has been criticized on methodological grounds and has been perceived by the academic community as placing too much emphasis on the positive aspects such as stating that a majority of the administrators at the top 50 schools rated their facilities as good to excellent (the number was actually 54 percent). The study also ignored plant debt as an issue which seems to have grown sharply in recent years. Thus, the survey has created the complications noted in Senate Report No. 100-189. The NSF is currently conducting a more scientific survey which should be completed by October, 1988.

In a study published in Feburary 1986 and titled "Report of the White House Science Council", the Office of Science and Technology Policy reported on the findings of the Panel on the Health of U.S. Colleges and Universities. The report begins by stating:

> The health of the U.S. society is uniquely coupled to that of its universities. To a greater degree than any other country this Nation looks to its universities both for new knowledge and for young trained minds to use it effectively. But just at a time when much is expected of our universities, after more than a decade of retrenchment and belt tightening, they find themselves with obsolete equipment, aging facilities, and shortages of both faculty members and students in many important fields.

The Report further states:

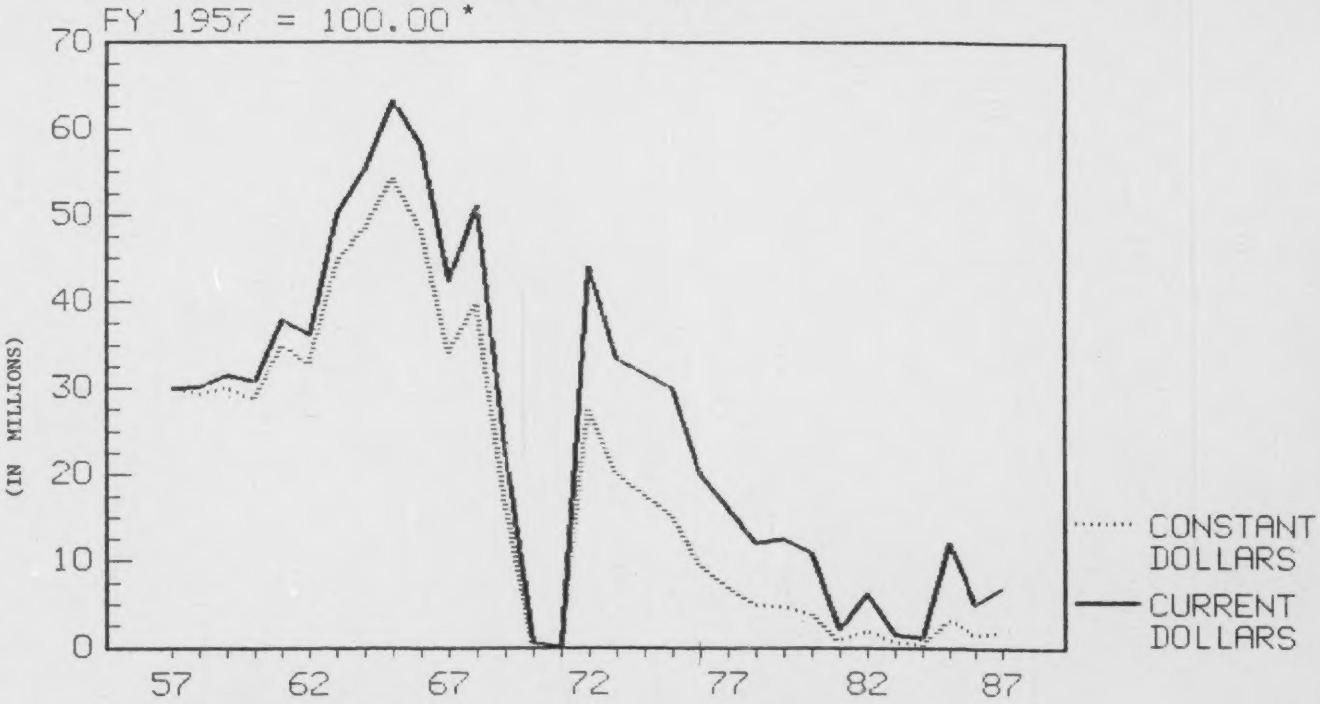
> The inadequacy and decay of the physical plant, and the obsolescence of the equipment pool have been extensively documented in recent years. There can be little doubt that they severely limit the research productivity and creativity of the universities.

The Panel believed "additional support is urgently needed to reverse the decay in physical plant and obsolescence in research equipment that has occurred in the past decade." The Panel estimated the minimum program scope to address the infrastructure shortfall at $10 billion over the next 10 years, $5 billion from federal sources and $5 billion from non-federal sources. The Committee feels that Congress can point with pride to its support in recent years of shared instrumentation programs at NIH which have helped alleviate the instrumentation shortfall in the health sciences. However, this is not the case for facilities needs.

In July 1985, some 200 leading college and university administrators, researchers, industrial and government officials, and representatives of professional societies met to discuss approaches to meeting the need to modernize deteriorating and obsolete research facilities. The conference and its report, "Academic Research Facilities: Financing Strategies", were supported by the National Science Board, Office of Science and Technology Policy, and the Government-University Research Roundtable. The conference reported that "No matter what the precise estimate, American research efforts are lagging far behind potential opportunities and are certain to suffer in the future if steps are not taken soon to refurbish existing facilities and build new ones." A recommendation emerged from the conference to support adoption of a federal facilities grant program embodying the concept of the Fuqua bill, H.R. 2823. The conference participants strongly endorsed three features: the program should be funded by new money; there should be merit review, and there should be a matching requirement. There was a lack of a consensus regarding merit review criteria, but there was considerable concern over the deleterious effects of congressional earmarking practices in this area.

There is consensus on how the current shortages in facilities have occurred. Federal grant support for health research facilities peaked in 1965 (see graph and table) with funding through the Health Research Facilities Act of 1956. There was a lapse in funding in 1972 as there was no appropriation and the Act was allowed to lapse. Significant categorical funding was received in 1972 through construction authority given to NCI in the National Cancer Act of 1971, but appropriations were quite low after 1980. Compare this picture with the growth in support for NIH research and training from 1957 to 1988 (see graph and table). Overall, direct Federal outlays for R&D plant, as a percentage of total Federal R&D, declined from nearly 7 percent of the total in 1965 to less than 1 percent in 1983. While a great deal of non-federal support has been forthcoming, it has not been sufficient to meet maintenance, renovation, and expansion needs as Federal construction suport has been withdrawn from a growing biomedical research enterprise. Moreover, as noted by the White House Panel, university administrators have allowed facilities needs to go unmet in order to maintain research productivity by protecting personnel and equipment. Clearly, research priorities are personnel, equipment, and facilities, in that order.

NIH Construction Grants
FY 1957 - 1987



*Constant dollars are based on the
GNP Implicit Price Deflator

FY 1957 - 1987 NIH CONSTRUCTION GRANTS, BY FISCAL YEAR

FISCAL YEAR	CURRENT DOLLARS	CONSTANT DOLLARS*	GNP DEFLATOR*
957	30,000	30,000	100.00
1958	30,200	29,377	102.80
1959	31,572	30,040	105.10
1960	30,786	28,665	107.40
1961	37,990	34,991	108.57
1962	36,230	32,787	110.50
1963	50,103	44,544	112.48
1964	55,283	48,443	114.12
1965	63,248	54,271	116.54
1966	58,053	48,394	119.96
1967	42,284	34,081	124.07
1968	51,077	39,770	128.43
1969	22,750	16,810	135.34
1970	531	371	143.21
1972	44,053	27,699	159.04
1973	33,478	20,054	166.94
1974	31,692	17,598	180.09
1975	30,000	15,105	198.61
1976	20,000	9,331	214.34
1977	16,000	6,914	231.43
1978	12,000	4,846	247.65
1979	12,452	4,630	268.97
1980	10,814	3,696	292.57
1981	2,027	630	321.84
1982	6,225	1,803	345.27
83	1,590	417	359.88
1984	1,000	268	373.55
1985	12,069	3,130	385.64
1986	4,954	1,249	396.56
1987	6,900	1,694	407.21

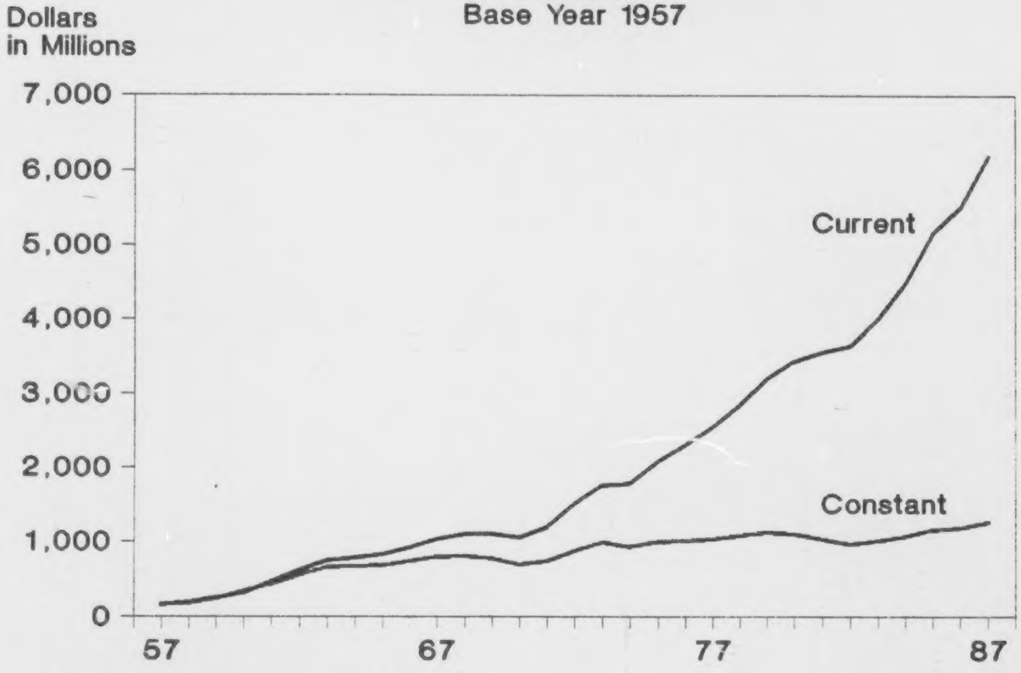
IMPAC - - SAB/DRG -- IRS PROGRAM RFMNG6B5

ALL AMOUNTS ARE IN THOUSANDS OF DOLLARS

* BASED ON IMPLICIT PRICE DEFLATOR FOR GROSS NATIONAL PRODUCT FY 1957 = 100.

Total NIH Appropriation in Current and Constant Dollars,

FY 1957-1987
Base Year 1957



Source: NIH Management Databank

OSPL May 1988

NIH APPROPRIATIONS
(Excluding Programs Transferred Out)
In Thousands of Dollars

	Current Dollars	Constant Dollars (1957=100)
1957	161,576	161,576
1958	189,329	184,841
1959	255,436	244,594
1960	343,382	322,103
1961	468,239	429,998
1962	630,790	566,352
1963	756,704	661,299
1964	793,293	678,542
1965	831,091	690,205
1966	929,931	745,376
1967	1,045,956	803,291
1968	1,111,461	814,903
1969	1,118,153	778,094
1970	1,061,007	694,784
1971	1,212,847	750,638
1972	1,506,156	887,950
1973	1,762,565	991,740
1974	1,790,425	947,227
1975	2,092,897	1,000,275
1976	2,302,126	1,023,874
1977	2,544,078	1,047,970
1978	2,842,936	1,090,405
1979	3,189,976	1,130,503
1980	3,428,935	1,107,015
1981	3,569,406	1,043,660
1982	3,641,875	980,387
1983	4,023,969	1,019,798
1984	4,493,588	1,075,079
1985	5,149,459	1,166,377
1986	5,498,454	1,193,154
1987	6,182,910	1,278,886

The Committee finds that the current deficit is serious and needs urgent attention lest it reach crisis proportions. The Committee believes that it is reasonable and appropriate that the Federal Government share in the cost of health research facility construction and maintenance. Recent experience shows it is necessary, and given that NIH supports over two-thirds of health research and development in universities, it is reasonable. Furthermore, it would be unreasonable to expect the non-federal sources to shoulder the entire burden for national priorities. The Committee further finds that this question is moot in as much as the Congressional Research Service reported in its 1987 study, "Bricks and Mortar: A Summary and Analysis of Proposals to Meet Research Facilities Needs on College Campuses" that in "FY 1987, congressionally earmarked funds for university research facilities totalled $145 million." The pork-barrel process is at best an inefficient and haphazard method to address such a critical need.

The Committee believes that a matching grant program located in the Division of Research Resources with the Federal part being typically no more than 50 percent for any one facility is appropriate. This represents a reasonable estimation of the Federal responsibility to support construction and maintenance at health research and training facilities conducting NIH supported research. The matching requirement should have the additional advantage of stimulating the availability of non-federal support. The matching requirement could be reduced for a center of emerging excellence where both the need and the potential contribution were exceptional. With the program located in the DRR, the entire spectrum of university and non-profit biomedial research institutions will be eligible. It was not the Committee's intention that this program supplant any construction authority granted to a categorical institute or agency, or that this program be captured by any one discipline, agency, or group of institutions.

The initial authorization of $150 million seems modest given the estimates of funding needed just to correct the deficit; however, no sound assessment of the extent of the need currently exists. This level of funding would allow a program to be established and contribute to meeting $300 million of facilities needs with the matching requirement. Furthermore, the response to this initial limited program will in itself serve as a measure of the need. The FY 1988 expenditures for university research and development facilities and instrumentation are projected at $940 million for the Department of Energy and $270 million for the military. Facilities needs for disease research are no less urgent than those funded by these other departments.

The Committee has assured that the grant applications considered under this program will be peer reviewed in the same manner as other NIH grant programs. The fundamental principle of NIH awards, that the primary criterion be scientific excellence, shall be observed. In determining overall priorities as a part of the peer review process, need shall also be considered. Generally, institutional need shall be based on the adequacy—or inadequacy—of the institution's current facilities to house the research and training that is planned by the institution and can reasonably be expected to be done. The Committee expects the Director of the Division of Research Resources to develop appropriate review criteria.

It is also important that emerging centers of excellence be able to share in this opportunity. The potential of minority schools and so called "have not" institutions to contribute in important ways to biomedical research should not be overlooked or underappreciated. Centers of emerging excellence should also be looked on by the NIH as centers of opportunity. For this purpose, the Committee has devised additional criteria to be considered for institutions that may lag behind in their institutional development or which have faced significant barriers to their development.

An emphasis and priority should be placed on the potential of such institutions to develop into significant contributors to the NIH effort. Institutions which are ready to bootstrap themselves to a higher level of capability should be given special consideration. The Committee has a special interest in those institutions which have demonstrated a special commitment and productivity in the education and training of black or other underrepresented minority health scientists. The Committee perceives that those institutions which have already begun developing needed infrastructure and productive research projects with the assistance of programs like Research Centers in Minority Institutions have demonstrated the kind of potential and achievement to be considered emerging centers of excellence. Special consideration should also be given to institutions that have shown the potential to contribute to meeting special national needs or to correcting regional deficits in biomedical research and training opportunities.

It is not, however, the Committee's intention that an institution be given a building in order to begin a research program. The facility should be one of the last pieces of the biomedical research and training puzzle, not the first, to be put into place. Moreover, no award should be made failing the reasonable expectation that meritorius biomedical research and training would result.

The Committee feels that there will have to be unusually broad presentation on the peer review and programmatic review committees covering this program. Because of the need to provide facilities funding to institutions of various types (medical centers, university laboratories, dental schools, etc.), it is important that these committees have expertise representing a cross-section of different fields and institutions. These committees should necessarily include members with:

a. experience in the planning, construction, financing and administration of institutions engaged in the conduct of research in the biomedical or behavioral sciences;

b. familiarity with the need for biomedical or behavioral research facilities;

c. familiarity with the need for research facilities in a broad range of health professions disciplines;

d. and experience with emerging centers of excellence.

In addition, the Committee anticipates that technical consultants will be employed from time to time as necessary where outside expertise is required.

The Committee expects that the decisions to move applications from emerging centers of excellence that have received scientific and technical merit approval into the pay range will be made by the Director with the advice of the Advisory Council at the second level of review. The Committee did not want to tie NIH administrators' hands in making judgment calls, so no earmark was included in bill language. However, the Committee anticipates that 15 to 20 percent of the appropriated funds would be used to support emerging centers of excellence with approximately one-third to one-half of that amount going specifically to minority institutions.

BIOMEDICAL ETHICS CENTERS

The Committee is cognizant of the fact that not all the difficulties in biomedical research are resource related. The power of modern science is presenting society with choices never before available. More and more, biomedical research is touching on issues that are ethical in nature. There are risks involved with present-day medical research. If we move hurriedly and blindly ahead, individual and societal rights may be abrogated. Yet, if we fail to move ahead at all, thousands of people may die that could have been spared as a result of research breakthroughs. These issues need to be fully explored and evaluated to provide guidance.

The Committee feels that input into this process from ethicists is greatly needed if we are to make the most of our opportunities and resources without violating moral precepts. This goal will be achieved through the creation of an extramural Centers for Biomedical Ethics program to be administered by the Division of Research Resources. Five extramural centers are proposed for support, with one to be awarded in each major region of the country. The centers will be responsible for the study of ethical issues surrounding medical research, health care delivery, and new technologies; their functions will include study, analysis, evaluation, and information storage and dissemination.

FETAL RESEARCH

Ten years ago, concerns over abuses caused a virtual elimination of Federal support for this area. However, using other sources of funding, researchers have been able to advance this field to the point where thousands of fetuses are saved. Treatments for conditions like urinary tract obstruction and hydrocephalus which formerly would have caused either death or disability have now been performed successfully in utero. Blood incompatibilities have also been treated prior to birth through exchange transfusions. These developments are greeted with excitement by the members of the Committee. Little of this research has been supported with federal dollars. The Committee notes that numerous researchers in the field who are developing fetal therapies are bypassing opportunities for NIH funding because of a misunderstanding of the regulations which delineate the existing DHHS restrictions on fetal research. The Committee is concerned that for research conducted using private support, neither the observance of moral precepts nor the quality of the research are assured by oversight outside of the performing institution. Federally sponsored research in this area would undergo rigorous ethical and scientific review at the national level. In addition, such important areas of research should not be denied the benefits of federal funding, especially when the basis for the absence of federal funding is only confusion and misunderstanding.

The Committee hopes to bring some clarity to the current confusion surrounding federal regulations and funding for fetal research. It seeks to clarify which research is eligible for federal funding and to bring reseachers who clearly are eligible under the umbrella of federal programs. The Committee seeks to encourage researchers who are unsure about the eligibility of their projects to step forward and engage in a dialogue about whether their projects conform to existing federal regulations and are therefore eligible for funding. The Committee is seeking a mechanism that would allow researchers to engage in this discussion before they embark on the time consuming activity of composing lengthy research grant proposals. In addition, given the startling progress in areas of research affected by existing federal regulations, the Committee feels it is time to reexamine the issues raised by fetal research to determine whether existing regulations remain appropriate. The Committee believes it is important to both adhere to ethical principles and continue to realize the full potential to save lives.

To these ends, three provisions have been made. First, a study of the issues surrounding research involving fetuses is to be made by the National Academy of Sciences. Second, the Secretary is mandated to establish an Ethics Advisory Board to advise the Secretary—and researchers in the field—regarding the interpretation of existing regulations and to make recommendations to the Secretary on the suitability of existing regulations. Third, during the period during which this process is under way, the moratorium on the Secretarial waiver is extended.

It has been over a decade since the report and recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "Research on the Fetus" (1975). Current federal regulations were based on the recommendations contained in that report and also date from that time. Over the last decade, there has been impressive progress in research methods and techniques enabling medical scientists to make exciting progress in a number of areas of medicine which effect fetal health and development. The Committee intends that there be a review of the scientific progress in the field of fetal research, including the area of fetal therapy, and that this report define the scientific, ethical, and funding issues which confront our country in light of this rapid progress. The report should address existing federal regulations regarding fetal research and make recommendations about whether or not any changes are warranted in these regulations.

The role of the Ethics Advisory Board will be to answer questions about the suitability of specific projects for federal funding thereby saving researchers the preparation of extensive grant applications before they may determine their eligibility. The Committee hopes that researchers will come forward easily, and early on in the genesis of their research ideas, so that little time will be wasted seeking federal funding if that is not possible under existing regulations. The Committee anticipates that some areas of research on fetal therapy and human fetuses will be identified that meet the test of current regulations but which are not receiving federal funds. The EAB will function as an interpretive body which will give counsel to researchers before their proposals are turned into grant applications. It will also issue recommendations to the Secretary. The Committee looks forward to a reexamination of the regulations regaring fetal research by the Ethics Advisory Board based on the report of the National Academy of Sciences once the report is completed. The Committee hopes to have the recommendations of both the Academy and the Board within two years regarding whether any updating of regulations is necessary. Until that time, the moratorium on waivers is extended.

The Committee anticipates that the National Institute for Child Health and Human Development might also seek to consult the new EAB. The Committee hopes that the National Institute of Child Health and Human Development will do so and that this consultation may help lay the groundwork for new grant programs to advance this field, especially the support of research on promising fetal therapies. The Committee hopes that the NICHD will begin to prepare for this activity.

SENIOR BIOMEDICAL SCIENTIST SERVICE

The Committee is also concerned by reports that government salary caps are causing severe recruitment and retention problems for NIH's intramural program. This program has long been behind industry in terms of what it could offer its scientists as salary and benfits, but in the last few years it has fallen far behind the pace set by universities as well. Top NIH scientists and institute directors can attract university offers doubling or tripling their government pay. Universities can also offer researchers more space and personnel, and greater administrative flexibility than can a government laboratory.

The Committee feels that this program must be maintained as a national resource of world class stature. As a minimum, the huge salary imbalance must be addressed. Establishment of the Senior Biomedical Scientific Service will offer a partial offset. The Committee hopes that by raising the maximum salary to 110 percent of the annual pay rate in effect for level I of the Executive Salary Schedule that the attractiveness of NIH as a career alternative will be significantly improved. The benefits of the Senior Scientist Service would also be available to senior scientists at the Alcohol, Drug Abuse, and Mental Health Administration, the Centers for Disease Control and the Food and Drug Administration.

NATIONAL INSTITUTE ON DEAFNESS AND COMMUNICATION DISORDERS

In addition to issues that affect all of health science research, the Committee finds that there are individual scientific areas of promise that could make great strides in contributing to health if given additional attention and emphasis within the NIH. One of the most striking examples is research on deafness and other communication disorders. This area is supported by a major division of the National Institute of Neurological and Communicative Disorders and Stroke and represents 13 percent of NINCDS' budget. Nevertheless, the national attention this area has drawn recently has underscored the inconsistency between the support given to this area and the prevalence of these disorders.

Over 20 million people suffer from hearing disorders, and the number of afflicted individuals rises to more than 28 million when other communication disorders are considered, one-tenth of the United States population. Deafness is the most common congenital disorder, affecting 1 in 1000 children. Of the hearing impaired, 4 million are senior citizens, and as the population ages, this number will rise over 10 million as we move into the next century. Yet, it is estimated that biomedical research support on deafness and other communication disorders amounts to only two-tenths of one percent of the costs.

The Committee feels that a separate institute is necessary to provide this field with the visibility, focus, and the program and research support needed to move research on deafness and other communication disorders up to its present day potential. Enough has not been done in the past, nor is it likely that enough will be done in the future without such a structural change. The NINCDS has program responsibilities in a number of important areas, including multiple sclerosis, Alzheimer's disease, epilepsy, Parkinson's disease, stroke, and cerebral palsy in addition to communication disorders. Program development in deafness and other communication disorders has and will likely continue to lag behind in emphasis and support while within a larger institute.

There is also felt to be a serious problem with the development of young clinical investigators, and the lack of sufficient clinical research centers with a major training component able to train these investigators in the otolaryngological disorders. It has been noted that there are probably less than 50 physicians currently trained and funded for active on-going clinical investigation in this field; most of those funded clinical investigators are older and the environment is such that fewer and fewer young academicians are being drawn toward an investigative career. Associated with this is an attitude or pessimism regarding the attraction of sustained funding for clinical investigators, and a dearth of clinical research centers with a training component. The Committee believes that a strategy must be developed to give a high priority to establishing a "critical mass" of trained clinical investigators. The Committee recognizes the importance of fields such as audiology and behavioral science in the overall progress of research in this field and supports inclusion of researchers in such fields in training efforts. The new Institute should focus on these needs through a wide range of research training awards and the development of clinical research center development grants and sustaining grants. The new Institute's leadership should work closely with the leadership of the various otolaryngologic, speech and hearing, and other appropriate organizations to develop such programs in the areas of hearing, balance, speech, language, voice chemosensory and related disorders.

The field of ear research is poised to take off. While training is a priority, there now exists a cadre of good researchers not present ten years ago. The new National Institute on Deafness and Other Communication Disorders visibility should attract even more trainees to this area. One aspect in critical need of advancement, however, is the incorporation of modern technology into this field. The advances in technology are there and the advances in ear research are there. The NIDOCD will bring them together as part of a comprehensive research plan to be developed for this field. The provisions for a data system and an information clearinghouse will greatly enhance prevention and treatment efforts. The Committee believes that the creation of this new Institute will provide the same stimulus to this field that the creation of the National Eye Foundation gave to vision research.

It is the Committee's intention that only the deafness and other communication disorder programs of NINCDS would be shifted to the new institute. For the purposes of this structural change, no other NIH program in this or a related area is to be affected. However, it is the Committee's intention that maximum savings be obtained by moving the NINCDS communication disorder programs into the new institute as efficiently as possible. Following the transfer, the name of NINCDS shall become the National Institute of Neurological Disorders and Stroke.

It is the Committee's expectation that NINCDS will continue to be involved in grants, research training and research programs dealing with neurogenic speech and language disorders. These disorders are intimately connected to the functioning of the brain and neurological processes. Many neurological diseases and disorders, such as Alzheimer's disease, Parkinson's disease and cerebral palsy, have devastating effects upon an individual's ability to communicate.

Given the close relationship of speech and language in such instances to neurological disorders, the Committee encourages close coordination between the institutes. Thus, the Committee expects that the new NIDOCD and the neurology institute will collaborate in areas of study where clear overlap exists, as occurs in other biomedical research areas within the NIH as well as across governmental agencies.

Furthermore, the Committee expects that NINCDS will continue to provide staff at an appropriate organizational level, adequate to both conduct important research in these areas and to preserve recognition of ongoing involvement with neurogenic speech and language disorders.

The Committee also recognizes the important role the National Institute for Occupational Safety and Health of the Centers for Disease Control plays in directing and coordinating research to combat work-related diseases and injuries. The Committee supports the statutory basis for these responsibilites of NIOSH as mandated by the Occupational Safety and Health Act of 1970 (Public Law 91–596). One of the Institutes top ten priorities for research is noise-induced hearing loss. Nothing in this legislation is intended to diminish, duplicate or remove the research activities of NIOSH in this area. NIOSH is encouraged to continue its excellent research in the area of occupational and environmental agents that influence hearing and other communication processes, including its research into methods by which industry can monitor and control noise and chemical agents that may influence hearing and other communication processes.

CENTER FOR MEDICAL REHABILITATION

Another area of considerable promise is medical rehabilitation research. Despite the obvious importance of this field to health care, it lacks a Federal entity devoted to its research and training needs and priorities. The National Institute for Disability and Rehabilitation Research funds research in this field as a part of its overall mission. NIDRR is located in the Department of Education, and thus, it has strong educational and vocational priorities. In 1980 when the Department of Health, Education, and Welfare was split and the Departments of Education, Health and Human Services were established, the National Institute for Handicapped Research (renamed NIDRR in 1986) was located in DOE.

The NIH supports approximately $107 million in medical rehabilitation research; however, there is no central administrative or coordinating entity at NIH. Many of the NIH institutes fund projects in this area, but most are located in the National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Child Health and Human Development, and the National Institute of Neurological and Communicative Disorders and Stroke. The researchers in this field feel that, while the individual efforts of the categorical institutes are excellent, there are gaps in coverage and the generic aspects of this discipline, such as training, are not attended to, nor are the applied and clinical aspects fully covered. Moreover, they feel there is no appropriate locus for an administrative entity for medical rehabilitation research within one of the categorical institutes. Medical rehabilitation research relates to medical care focused on disability rather than disease or organs and on function; it cuts across various organ systems or diseases. The NIH institutes are primarily disease or organ specific; the National Institute of General Medical Science's portfolio is scientifically generic, but is focused on basic science, not on applied and clinical resarch of the type most often associated with medical rehabilitation research. The researchers do feel, however, that the NIH itself is the proper locus for an entity to administer to their needs. They believe that the model for scientific standards that exists in NIH would substantially enhance the prospects for scientific growth and development of medical rehabilitation research.

The Committee finds that this diffuse situation represents an unusually promising opportunity. The leaders in this discipline are highly dedicated to advancing their field, and all that is lacking is an administrative structure to facilitate their efforts. Consequently, the Committee is recommending the creation of a National Center for Medical Rehabilitation Research. It is expected that the Center will support projects and training in medical rehabilitaion research, including behavioral studies, epidemiology, and health services research. However, it is expected that a major effort of the Center will be planning and coordination. The activities of the Center should not supplant any current efforts at the NIH or at NIDRR in medical rehabilitation research, expect by mutual agreement. Rather, it is intended that the augmentation and coordination provided by the Center will stimulate medical rehabilitation research in the categorical institutes. It is the Committee's intention, for example, that the Center be involved in the joint funding of projects with other NIH agencies.

The Committee recognizes that research in the field of medical rehabilitation, like medical rehabilitation services, has been and continues to be multi-disciplinary. Allied health disciplines such as speech and language, physical therapy, occupational therapy, as well as the disciplines of psychology, engineering, counseling and social work are all involved in this field and should be trained and supported to do research. It is the Committee's intention that these disciplines be included in the constituency for this Center and that developmental and congenital disabilities, as well as disabilities generated by disease and trauma, be covered in the plan.

GERIATRIC CENTERS

The Committee also recommends the development or expansion of geriatric centers by the National Institute on Aging. There have been tremendous advances in aging research in recent years; many clinically important discoveries have been made. The focus of the geriatric centers is to be research in geriatrics and the training of physicians to do research in geriatrics. The Committee anticipates that the Centers will also provide training in geriatrics and in research in geriatrics to other physicians and to students of health professions. The Committee recommends that the geriatric training programs administered by the Health Resources Services Administration and the research programs administered by the National Institute on Aging be located whenever possible at the same institutions. Such centers should enhance the translation of research findings in geriatrics into better patient care.

THE NATIONAL INSTITUTE ON DIABETES, DIGESTIVE AND KIDNEY DISEASES AND ENDOCRINOLOGY

The Committee hopes to improve the support and recognition for endocrinology research by increasing its visibility in the context of its current home. The National Institute of Diabetes and Digestive and Kidney Diseases has been renamed the National Institute of Diabetes, Digestive and Kidney Diseases, and Endocrinology. Also, the termination clause for the National Advisory Boards of NIDDK has been removed. These Boards have provided critical service to their respective areas and should continue. The Committee believes it is important to keep the number of trainees in the field of digestive diseases at the level recommended by the National Academy of Sciences and urges that training receive generally high priority. The Committee feels the Digestive Diseases Advisory Board should recognize the importance of nutrition and nutrition research in regard to the health of the U.S. population and to include that concern in its agenda.

NATIONAL RESEARCH SERVICE AWARDS

The Committee recommends a 27 percent increase in the authorization level for National Research Service Awards. This increase reflects the need to increase stipends for these awards and to increase the number of awards. Stipend levels must be increased if we are to attract the brightest minds into health research. There has been no cost of living increase in the stipends since 1984 and the income of trainees has been further lowered as a result of recent tax law changes. In particular, trainee stipends need to remain comparable to average pay for medical residents in order to attract physicians to research; currently, a resident must accept a reduction in pay if a research path is chosen.

Although the size of the biomedical research enterprise has grown dramatically in the last ten years, there has been essentially no growth in the number of trainees during this period. The number of NIH trainees is substantially below the National Academy of Sciences recommended levels. NIH anticipates funding 11,300 trainees for 1989; the NAS recommended level is a little over 13,000. A large part of the discrepancy between the levels recommended by the NAS and the current number of trainees is accounted for by a shortfall of 1,000 trainees in the fields of Alcohol, Drug Abuse, and Mental Health. The Committee's increase in authorization would make it possible to bring the numbers of trainees in these fields up to the recommended levels (an estimated cost of $25 million). The Committee feels that in light of the AIDS epidemic it is essential to do this. This view is underscored by recent statements of the Chair of the President's Commission on AIDS emphasizing the importance of research efforts in the area of drug abuse.

The Committee is also concerned about the stimulation of research in areas of importance in science and medicine which do not fit neatly into the categories as defined by existing categorical institutes. The Committee directs the NRSA program to develop approaches to identifying and supporting promising young talent in fields such as primary care, public health, surgery, general internal medicine, medical rehabilitation, and behavorial studies to provide opportunities for training for such individuals for research careers. The Committee also encourages support for promising Ph.D. researchers in the Allied Health fields such as nutirition, audiology, and physical therapy. Nutrition is an example of a field which may suffer because of the lack of clear alignment with a single categorical institute. Sites which receive institutional training awards seem to be the likely centers from which identification, recruitment and integration of such individuals into training programs could be accomplished. Primary care has been an ongoing area of concern for the Congress. The Committee is also concerned about the shortage of researchers in areas such as environmental epidemiology, biostatistics, environmental toxicology, chronic disease and behavorial science.

CENTER FOR NURSING RESEARCH

Another area of personnel problems is the national nursing shortage. While it is generally accepted that salary levels are part of the problem, the Committee believes another important factor is the role of the nurse in patient care. An opportunity exists for the National Center for Nursing Research to make a contribution to the data base which is necessary to tackle this problem. The authority given to NCNR to support demonstrations of innovative models of nursing care should provide the chance for the Center to support efforts to examine this pressing national problem. The

Committee anticipates that the authority for fund demonstration programs will have many other applications as well.

The facilities problem for nursing schools is particularly acute. The Committee believes this field will benefit from having its own construction authority and that has been added.

NATIONAL CANCER INSITUTE

The Committee finds evidence for hope in the war on cancer effort. Diagnosis, treatment, and prevention efforts are progressing. Research advances are compounding, establishing a basis from which cures will surely come. At the same time however, 870,000 new cases and 450,000 deaths each year demand that an expanding effort be made. Therefore, the recommended 16 percent increased in authorization level for the National Cancer Institute includes 13 percent needed for current service and 3 percent for real growth.

The Committee commends the National Cancer Institute for the multidisciplinary approach to cancer control which has been increasingly pursued. The importance of research in the areas of nutrition., environmental influences, and behavior is recognized by the Committee and the efforts of the NCI in this regard are encouraged.

The Committee acknowledges the importance of public education to effect changes in behavior for better health. The Committee commends the work of the Cancer Control program in disseminating useful information in this regard. However, the Committee feels that care needs to be taken to avoid duplication of effort by different branches of the Public Health Service. The Committee also believes it is more appropriate for NIH Institutes to emphasize the dissemination of information to health professionals who would then offer that information to the public rather than attempt to become a resource for public education.

The Committee is aware that a physicians's choice of the most effective therapeutic approach is often dependent on the information received from the diagnostic evaluation of the patient. Therefore, research to improve detection and diagnosis is critical. New diagnostic imaging techniques are improving the ability to detect small lesions and to provide better staging information. The Committee hopes that the National Cancer Institute will utilize a portion of the increased authorization to expand its support of research in the field of diagnostic imaging.

The Committee is also aware that promising new imaging technologies are helping scientists and physicians to better understand the causes of cancer, heart disease, Alzheimer's disease, and many other diseases and disorders. As such, the contributions of this field cut across most of the NIH Institutes. The Committee encourages the NIH to create a Diagnostic imaging coordinating committee which will be responsible for coordinating on-going research, as well as to develop a long-range research plan for diagnostic imaging.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The Committee recommends a similar increase based on the 1988 appropriation level for the National Heart, Lung, and Blood Institute. Federal support for this institute has resulted in a 43 percent drop in mortality from coronary heart disease since 1972. The expanded support should result in similarly impressive progress in NHLBI's research programs.

ASSOCIATE DIRECTORS FOR PREVENTION

The Committee would like to express its concern regarding the system of Associate Directors for Prevention. The Committee notes with displeasure the small the small amount of funding available to the office of the Associate Director for Prevention within the Director's Office and believes it is clear that this is an unnecessary and binding limitation on the influence of that office. The Committee prefers that the funding and staffing of this office be increased to a level more commensurate with the importance of its responsibility.

It has also come to the attention of the Committee that the individual institute Associate Directors for Prevention are, in most cases, also squeezed by inadequate staff and funding. It is the Committee's intent that the Associate Directors for Prevention serve as active promoters of the disease prevention and health promotion research of the National Institutes of Health and that research and programs in the area of health and behavior be given heightened attention. It is also intended that the individuals appointed to fill these positions have this as their full-time responsibility and have appropriate experience in prevention, public health, or health and behavior in their professional background.

NATIONAL LIBRARY OF MEDICINE

Several changes are recommended to aid the National Library of Medicine. The authorization level of the medical libraries assistance program is maintained at the 1988 level for 1989, but this is still substantially greater than the 1988 appropriation level. The $500,000 grant cap is lifted in recognition of how the size of these requests has grown, and NLM is granted construction authority. NLM is also granted authority to support demonstration projects for the development of new educational technologies which will assist in the training of medical personnel and in speeding the transfer of laboratory advances to clinical applications. Finally, to assist NLM in obtaining members for its Board of Regents, new members after 1988 will be Presidential appointees. The Committee hopes these changes will assist NLM in maintaining its stature as the premier medical library in the world.

HEARINGS

The Committee held a hearing on the Reauthorization of the National Institutes of Health on March 29, 1988. The agenda and witness list of the hearing follows.

PANEL I: ADMINISTRATION

James Wyngaarden, M.D., Director, National Institutes of Health, Bethesda, MD, accompanied by Steven A. Rosenberg, M.D., Chief of Surgery, National Cancer Institute, Bethesda, MD.

Ada Sue Hinshaw, Ph.D., Director, National Center for Nursing Research, National Institutes of Health, Bethesda, MD.

PANEL II: FACILITIES CONSTRUCTION

Chase Peterson, M.D., President, University of Utah, American Association of Universities, National Association of State Universities and Land Grant Colleges, Salt Lake City, UT.

David Satcher, M.D., Ph.D., President, Meharry Medical College, Nashville, TN.

PANEL III: RESEARCH: AREAS OF PROMISE

Cancer

John Ultman, M.D., Chairman, National Coalition for Cancer Research, Chicago, IL.

Medical rehabilitation research

Bruce Gans, M.D., Chairman, Department of Physical Medicine and Rehabilitation, Tufts New England Medical Center, Medford, MA.

Deafness and other communication disorders research

Ms. Marlee Matlin, Actress, Toluca Lake, CA.

Bruce J. Gantz, M.D., Professor of Otolaryngology, University of Iowa, Hospitals and Clinics, Iowa City, IA.

COMMITTEE ACTION

There were two amendments offered at the mark-up of S. 2222. The first was offered by Senator Metzenbaum to add "Endocrinology" to the title of the National Institute of Diabetes, Digestive and Kidney Diseases, to make it the National Institute of Diabetes, Digestive and Kidney Diseases, and Endocrinology. This was accepted by voice vote without objection. The second amendment, proposed by Senator Harkin, was to establish a National Institute of Deafness and Communication Disorders as a separate institute at the NIH and remove this area of research from the National Institute of Neurological and Communicative Disorders and Stroke which would then become the National Institute of Neurological Disorders and Stroke. This amendment was also accepted by voice vote without objection.

VOTES IN COMMITTEE

There were three votes pertaining to S. 2222 in Committee. The bill was brought up in Executive Session on April 13, 1988. It was presented as a Committee amendment in the form of a substitute. Two amendments were accepted unanimously by voice vote. The final vote was on the Committee amendment in the form of a substitute as amended. The measure was approved unanimously by voice vote.

COST ESTIMATE

1. Bill number: S. 2222.

2. Bill title: National Research Institutes Reauthorization Act of 1988.

3. Bill status: As ordered reported from the Senate Committee on Labor and Human Resources, April 13, 1988.

4. Bill purpose: The purpose of S. 2222 is to amend the Public Health Service Act to reauthorize programs relating to the National Research Institutes and to establish new programs.

5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1989	1990	1991	1992	1993
Estimated authorization levels:					
Biomedical and behavioral research facility construction grant	150	156	162		
Center for Biomedical Ethics	4	4	4	4	4
Fetal therapy and research	1	[1]	[1]	[1]	[1]
National Institute on Deafness and Other Communication Disorders	77	79	83	86	89
Centers of Geriatric Research and training	5	5	5	6	6
National Center for Medical Rehabilitation Research	28	26	27	28	29
Nursing Research Grant Program	2	2	2	2	2
Nursing research construction grant	3	3	4	4	4
National Cancer Institute (NCI)	1,587	1,654	1,720		
NIC control programs	84	88	91		
National Heart, Lung, and Blood Institute (NHILBI)	1,001	1,042	1,084		
NHLBI control programs	101	105	109		
National Library of Medicine	14	15	15		
National research service awards	350	365	379		
Sr. biomedical scientific service	4	4	4		
Total estimated authorization levels	3,410	3,549	3,689	129	135

[1] Less than $500,000.

[By fiscal years in millions of dollars]

	1989	1990	1991	1992	1993
Estimated outlays:					
Biomedical and behavioral research facility construction grant	42	108	138	107	43
Center for Biomedical Ethics	2	4	4	4	4
Fetal therapy and research	[1]	1	[1]	[1]	[1]
National Institute on Deafness and Other Communication Disorders	26	67	80	83	87
Centers of Geriatric Research and Training	2	4	5	5	6
National Center for Medical Rehabilitation research	4	27	26	27	28
Nursing Research Grant Program	[1]	2	2	2	2
Nursing research construction grant	1	2	3	3	4
National Cancer Institute (NCI)	652	1,455	1,658	1,006	172
NCI control programs	35	77	88	53	9
National Heart, Lung, and Blood Institute (NHLBI)	362	880	1,030	685	146
NHLBI control programs	37	89	104	69	15
National Library of Medicine	9	13	15	5	1
National research service awards	14	239	350	359	121
Sr. biomedical scientific service	2	4	4	3	1
Total estimated outlays	1,186	2,970	3,507	2,412	639

[1] Less than $500,000.

Note.—Details in these tables may not add to totals because of rounding.

The costs of this bill would fall within budget function 550.

Basis of estimate: The CBO assumes that all authorized amounts are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of historical spending data. This bill is subject to subsequent appropriations action.

S. 2222 would reauthorize the National Cancer Institute, NCI Control Programs, National Heart, Lung, and Blood Institute, NHLBI Control Programs, National Library of Medicine, and National Research Service Awards. A construction grant to support renovation and expansion of existing facilities or the construction of new facilities at extramural biomedical and behavioral research institutions would also be authorized. Authorization levels were stated in the bill for all of these programs.

S. 2222 would establish the National Institute on Deafness and Other Communication Disorders within NIH. Currently, this research is conducted through the National Institute of Neurological and Communicative Disorders and Stroke. The new institute would restructure the current program. Committee staff has indicated that the Committee's intent is to redirect funds to the new institute that otherwise would have been appropriated to the current program. The bill authorizes such sums as may be necessary to fund the new institute and includes the transfer of personnel, assets, and liabilities. For fiscal year 1989, authorizations are estimated to be $77 million, including $4.5 million for administrative expenses. The 1988 appropriation provided $71 million for deafness and other communications disorders. The 1989 authorization level was estimated by increasing the 1988 appropriation by the appropriate inflator and adding administrative expenses. Because of some start-up expenses in 1989, administrative expenses would be lower for fiscal years 1990 through 1993.

The bill would establish the National Center for Medical Rehabilitation Research on the NIH campus. Authorization levels were not stated in the bill for this center. NIH currently operates similar centers and estimates that the activity level for this new center would be comparable to the National Center for Nursing Research. The 1988 appropriation level for the National Center for Nursing Research was $23 million. The 1989 appropriation for the National Center for Medical Rehabilitation Research was estimated by increasing $23 million by the appropriate inflator and adding $2.8 million for administrative costs.

S. 2222 would establish at least five centers for biomedical ethics and several centers for geriatric research and training. These centers would not be located on the NIH campus. Authorization levels were not stated in the bill for these programs. Similar centers operated by NIH cost between $750,000 and $1 million each year. The costs in fiscal years 1989 through 1993 would be about $4 million in each year for five biomedical ethics centers. If five centers for geriatric research and training were established, NIH estimates that these centers would cost about $5 million in each fiscal year. Costs could be higher or lower depending on the number of centers established and the actual level of activity undertaken.

S. 2222 would institute a nursing research grant program and nursing research construction grants within the National Center for Nursing Research. Research into innovative nursing care models, the nursing shortage, and quality patient care would be funded through the grant program. The estimated authorization level is about $2 million for each fiscal year, 1989 through 1993. This funding level was determined by estimating the size of the average grant awarded by the National Center for Nursing Research and estimating the number of new awards to be funded. The construction grants would support building, acquiring, or renovating facilities and would be authorized at between $3 million and $4 million in each fiscal year. Costs could vary depending on the number of grants awarded.

The bill would allow the Secretary of Health and Human Services (HHS) to appoint a Fetal Therapy and Research Ethics Advisory Board and to conduct an 18 month study on the scientific, ethical, and funding issues involved in fetal therapy and research. The 18-month study is estimated to cost $750,000 and the advisory board would cost about $100,000 in each year.

The Secretary of HHS would be authorized to create a Senior Biomedical Scientific Service program to retain scientists within HHS. This program would raise the salary limit for senior scientists and is estimated to cost about $4 million for each fiscal year 1989 through 1991. The Public Health Service estimates that 500 scientists would fall into this category and that the initial salary increase would be about $8,000 for each scientist.

6. Estimated cost to State and local government: None.
7. Estimate comparison: None.
8. Previous CBO estimate: None.
9. Estimate prepared by: Lori Housman.
10. Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

REGULATORY IMPACT STATEMENT

This legislation is expected to have regulatory impact in only one area—fetal research. The bill requires the appointment of an Ethics Advisory Board in the Department of Health and Human Services to improve the administration of current regulations with regard to fetal research. The Board is intended to serve several functions: (1) to advise the Secretary on the interpretation of current regulations (2) to be a source of information for medical researchers engaged in—or contemplating research—involving human fetuses, and (3) it will make recommendations about any needed changes in existing regulations following a report by the National Academy of Sciences.

As a resource for medical researchers, the Board is expected to deliberate and answer questions which may arise about the suitability of specific research projects for government funding. The Committee anticipates that this will encourage some researchers who are not currently applying for federal funds because they fear they are not eligible under current regulations—but who are in fact eligible—to come forward and clarify this point without having to complete a grant application first. This procedure should contribute to an improved functioning of current regulations.

SECTION-BY-SECTION ANALYSIS

S. 2222—National Research Institutes Reauthorization Act of 1988 as reported by the Senate Committee on Labor and Human Resources

Section 1. Short title; Table of Contents

Section 1 of the bill cites the Act as the "National Research Institutes Reauthorization Act of 1988," and displays the table of contents.

Section 2. References to the Public Health Service Act

Section 2 of the bill identifies all references in the bill as being made to provisions of the Public Health Service Act (PHSA), except as otherwise specifically provided.

TITLE I—BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

Section 101. Biomedical and Behavioral Research Facilities

Section 101 adds a new "Part H—Biomedical and Behavioral Research Facilities" to Title IV of the Public Health Service Act. New PHSA section 499A authorizes the Director of the Division of Research Resources (DRR) to award grants to public and nonprofit private institutions to expand, remodel, renovate, or alter existing research facilities or construct new research facilities.

New section 499B establishes in DRR a Technical Review Board on Biomedical and Behavioral Research Facilities to advise on construction of facilities and to conduct peer review of grant applications. The section describes the membership of the Board (at least 12 appointed members plus an official of the National Science Foundation), their terms of service (staggered four-year terms), and their compensation. It sets forth the duties and activities of the Board in advising the Director and the DRR Advisory Council, conducting peer review of grant applications, and preparing an annual report.

New section 499C sets forth criteria for grant applications and awards. Applicant institutions must give assurances that they meet, or will soon meet, eligibility conditions established by the Director; that they will be using the research facility for at least 20 years; that they have sufficient funds to meet the non-Federal share of the construction costs and to use the facility effectively after construction; and that the proposed construction will either expand their capacity for research or improve or maintain its quality. In awarding grants, the Director shall consider the effectiveness of the proposed facilities in expanding and improving research capacity and quality; the quality of the research or training to be carried out; the institution's need for the facilities; the Nation's research and manpower needs; and the age and condition of existing research facilities and equipment. Special criteria are set out for institutions of emerging excellence. They must have a plan for research or training advancement and have one of the following qualifications: they carry out research and training programs that have a special relevance to a problem, concern, or unmet need of the United States; they have already demonstrated a commitment to enhancing and expanding their research productivity; or they have done productive research in spite of barriers to institutional development created by the underrepresentation of minorities in health science careers, the health status deficit of a large segment of the population, or a regional deficit in resources.

New section 499D makes provisions for payment of grant awards. The Federal contribution is limited to 50 percent of the necessary cost, except that the Director may waive this limitation in the case of institutions of emerging excellence. In determining the amount of grant awards, certain costs are excluded from the cost of construction.

New section 499E provides for the recapture of Federal grant payments if within 20 years after construction of a facility the owner ceases to be a public or nonprofit private institution, or the facility ceases to be used appropriately for research.

New section 499F prohibits Federal interference with the research, personnel, or administration of grantee institutions.

New section 499G provides that within 6 months after enactment of this Act the Director shall by regulation prescribe the eligibility criteria for grants and the conditions of approving applications.

New section 499H makes provisions for peer review of grant applications similar to the system of scientific peer review of research grants.

New section 499I authorizes appropriations of $150,000,000 for FY 1989 and such sums as necessary for FY 1990 and FY 1991.

New section 499J defines the terms "construction", "cost of construction", and "public or nonprofit private institution."

TITLE II—BIOMEDICAL ETHICS

Section 201. Centers for Biomedical Ethics

Section 201 adds a new "Section 481A—Centers for Biomedical Ethics" to subpart 1 (Division of Research Resources) of part E of Title IV of the Public Health Service Act. The Director of DRR is authorized to enter into cooperative agreements or to award grants for the development or expansion of no less than five extramural centers of excellence in biomedical and behavioral research ethics. The centers will analyze and disseminate information on biomedical ethical issues resulting from the conduct of research, the delivery of health care services and experimental therapy and procedures, and the use of new health care technologies.

Section 202. Fetal Therapy and Research

Section 202 amends section 498(c) of the Public Health Service Act concerning fetal research. The Secretary is mandated to appoint a 15-member Ethics Advisory Board to advise the Secretary and biomedical researchers regarding research on fetal therapies and research involving human fetuses. The makeup of the Board is specified. The Secretary is mandated to contract for an 18-month study of the scientific, ethical, and funding issues surrounding medical research on fetal therapy and involving human fetuses. The National Academy of Sciences shall be invited to apply for the contract. As part of the study, the recipient shall review the regulations on fetal research and analyze the biomedical and ethical implications of waiving the risk standard. The ban on secretarial waivers for fetal research is continued for two years.

TITLE III—NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Section 301. National Institute on Deafness and Other Communication Disorders

Section 301 amends Part C of Title IV of the Public Health Service Act by creating a new "Subpart 13—National Institute on Deafness and other Communication Disorders." The National Institute of Neurological and Communicative Disorders and Stroke is renamed the National Institute of Neurological Disorders and Stroke and its mission statement in Subpart 10 of Part C is changed to remove responsibility for research on disorders of human communication.

New PHSA section 464 defines the general purpose of the National Institute on Deafness and Other Communication Disorders.

New section 464A provides for the establishment of a National Deafness and Other Communication Disorders Program, to be guided by a plan to initiate, expand, intensify, and coordinate the activities of the Institute respecting disorders of hearing, balance, voice, speech, teaste, and smell. The Program shall provide for a variety of research activities on disorders of hearing and other communication processes.

New section 464B provides for the establishment of a National Deafness and Other Communication Disorders Data System and a National Deafness and Other Communication Disorders Information Clearinghouse.

New section 464C provides for the development, modernization, and operation of new and existing Multipurpose Deafness and Other Communication Disorders Centers. Centers are to conduct (1) basic and clinical research into all aspects of disorders of hearing and other communication processes, (2) training programs for health professionals, (3) information and continuing education programs for health professionals, and (4) information programs for the general public on detection, treatment, and prevention of hearing and other communications disorders. Centers may conduct programs on new methods of detecting individuals at risk of developing communication disorders, on disseminating research results, and on standardizing patient data and recordkeeping. Centers are to be distributed geographically and with respect to the special need for centers suited to serving the elderly and children. Centers may receive support for a maximum period of seven years, with possible extensions of five year periods.

New section 464D authorizes appropriations of such sums as are determined necessary by the Secretary.

Section 301 also makes provision for transfer of personnel, assets, and liabilities from the National Institute of Neurological and other Communication Disorders to the new Institute, and provides that all functions effective on the date of enactment of this Act shall continue. The effective date of this section will be October 1, 1988, or the date of enactment of this Act, whichever is later.

TITLE IV—NATIONAL INSTITUTE ON AGING

Section 401. Centers of Geriatric Research and Training

Section 401 adds a new "Section 445A—Centers of Geriatric Research and Training" to subpart 5 (National Institute on Aging) of part C of Title IV of the Public Health Service Act. The NIA is authorized to enter into cooperative agreements or make grants for the development or expansion of centers of excellence in geriatric research and training. These centers are to conduct research into the aging processes and related disorders, and conduct training programs to develop researchers in these fields. Centers are to be geographically distributed and located at institutions with proven research capabilities and emerging centers of excellence.

TITLE V—NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH

Section 501. National Center for Medical Rehabilitation Research

Section 501 adds a new "Subpart 4—National Center for Medical Rehabilitation Research" to part E of Title IV of the Public Health Service Act. New PHSA section 486A sets forth the general purpose of the Center in conducting and supporting research, training, and information dissemination with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of various physiologic systems ("medical rehabilitation").

New section 486B provides for the appointment of the Director of the Center.

New section 486C sets out the specific authorities of the Center in funding grants, cooperative agreements, contracts, clinical trials, model systems, centers, and multidisciplinary research, in coordinating its activities with those of other public and private agencies and entities, and in appointing peer review groups.

New section 486D requires the development of a comprehensive plan for medical rehabilitation research, which will identify research priorities and provide for the coordination of such research across NIH.

New section 486E provides for a Medical Rehabilitation Coordinating Committee composed of the directors of various appropriate NIH institutes. The Committee will make recommendations on the research plan and the activities of the Center.

New section 486F provides for a Medical Rehabilitation Advisory Council, to be composed of 18 qualified representatives of the public and 9 ex officio members who are Federal officials. The council will function in the same manner as other advisory councils to the national research institutes.

TITLE VI—NATIONAL CENTER FOR NURSING RESEARCH

Section 601. National Center for Nursing Research

Section 601 amends section 484 of the Public Health Service Act to expand the specific authorities of NCNR. NCNR may make grants for research or demonstration projects on innovative models of nursing care, problems relating to the national nursing shortage, and the quality of the nursing role in patient care. The Center may also make grants for the acquisition, construction, or renovation of facilities.

TITLE VII—NATIONAL CANCERS INSTITUTE

Section 701. Purpose

Section 701 amends section 410 of the Public Health Service Act to add research on rehabilitation from cancer to the statement of general purpose of NCI.

Section 702. Special Authorities of the Director

Section 702 amends section 413(b) of the Public Health Service Act concerning several of the special authorities of the Director of NCI. The Director may obtain the services of consultants in consultation with (rather than "with the approval of") the advisory council. The Director is given authority to appoint advisory committees to conduct peer review. New authority is granted for publication of information on cancer. The special bypass budget provisions are made permanent.

Section 703. National Cancer Research and Demonstration Centers

Section 703 amends section 414 of the Public Health Service Act to add research on cancer control to the responsibilities of the National Cancer Research and Demonstration Centers.

TITLE VIII—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Section 801. Information and Education

Section 801 amends section 420 of the Public Health Service Act to increase the focus of the institute's education and information programs on prevention of heart, lung, and blood diseases.

Section 802. Resources Program

Section 802 amends section 421 of the Public Health Service Act by adding a focus on rehabilitation from heart, lung, and blood diseases, and by directing NHLBI to support education and training programs, including continuing education and laboratory and clinical research training.

Section 803. National Research and Demonstration Centers

Section 803 amends section 422 of the Public Health Service Act to add a focus on rehabilitation to the responsibilities of the National Research and Demonstration Centers.

Section 804. Interagency Technical Committee

Section 804 repeals section 423 of the Public Health Service Act concerning the Interagency Technical Committee on Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources.

TITLE IX—NATIONAL INSTITUTES OF HEALTH

Section 901. Appointment and Authority of the Director

Section 901 amends section 402 of the Public Health Service Act to give the NIH Director authority to establish scientific program advisory committees.

TITLE X—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

Section 1001. Appointment and Authority of the Directors

Section 1001 makes technical changes in section 405 of the Public Health Service Act concerning the powers and duties of the directors of institutes and agencies of NIH; concerning the tax status of gifts to NIH; and concerning the establishment of technical and scientific peer review groups.

Section 1002. Advisory Councils

Section 1002 amends section 406 of the Public Health Service Act by making technical changes concerning the appointment of members of institute advisory councils, and concerning the membership of the National Cancer Advisory Board.

Section 1003. Authorization of Appropriations

Section 1003 amends section 408 of the Public Health Service Act to extend the authorization of appropriations for the National Cancer Institute and the National Heart, Lung, and Blood Institute for three years, FY 1989–1991. Authorizations for FY 1989 and set at $1,671,000,000 for NCI and $1,102,000,000 for NHLBI, and such sums as necessary for both institutes for FY 1990 and 1991.

TITLE XI—NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Section 1101. Redesignation of National Institute of Diabetes and Digestive and Kidney Diseases

Section 1101 amends Title IV of the Public Health Service Act to rename the National Institute of Diabetes and Digestive and Kidney Diseases as the National Institute of Diabetes, Digestive and Kidney Diseases, and Endocrinology.

Section 1102. Advisory Boards

Section 1102 amends section 430 of the Public Health Service Act to remove the termination provision pertaining to the institute's three National Advisory Boards.

TITLE XII—NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Section 1201. National Arthritis and Musculoskeletal Disease Programs

Section 1201 amends section 436 of the Public Health Service Act, specifically adding skin diseases to the description of the institute's program.

Section 1202. Multipurpose Disease Centers

Section 1202 amends section 441 of the Public Health Service Act to add a focus on rehabilitation to the responsibilities of the Multipurpose Arthritis and Musculoskeletal Diseases Centers.

TITLE XIII—NATIONAL LIBRARY OF MEDICINE

Section 1301. Board of Regents

Section 1301 amends section 466 of the Public Health Service Act to change the membership of the NLM Board of Regents from 10 members appointed by the Secretary to 13 members appointed by the President.

Section 1302. Authorization of Appropriations

Section 1302 amends section 469 of the Public Health Service Act to extend the authorization of appropriations for medical library programs for three years, FY 1989-1991. Authorizations are set at $14,000,000 for FY 1989 and such sums as are necessary for FY 1990 and FY 1991.

Section 1303. Grants for the Development of New Educational Technologies

Section 1303 amends section 473 of the Public Health Service Act to create a grant program for the development of new educational technologies. Funding may support such projects as computer-assisted teaching, information transfer from research to clinical applications, expansion of the uses of research databases, and testing of new technologies for training health care professionals in nontraditional settings.

Section 1304. Grants for Basic Resources of Medical Libraries

Section 1304 amends section 474 of the Public Health Service Act to authorize grants for the acquisition, construction, or renovation of facilities, and to remove the cap of $500,000 on these basic resources grants.

Section 1305. Grants for Establishment of Regional Medical Libraries

Section 1305 amends section 475 of the Public Health Service Act to authorize grants for the acquisition, construction, or renovation of facilities of regional medical libraries.

TITLE XIV—AWARDS AND TRAINING

Section 1401. National Research Service Awards

Section 1401 amends section 487 of the Public Health Service Act to direct that support be provided for multidisciplinary research training in disciplines not readily identified with existing categorical institutes. The authorization of appropriations for the National Research Service Awards is extended for three years, FY 1989-1991. Authorizations are set at $350,000,000 for FY 1989 and such sums as are necessary for FY 1990 and FY 1991.

TITLE XV—GENERAL PROVISIONS

Section 1501. Peer Review Requirements

Section 1501 amends section 492 of the Public Health Service Act to make technical changes in peer review requirements.

TITLE XVI—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

Section 1601. Biomedical Research

Section 1601 amends part A of Title III of the Public Health Service Act by adding a new "Section 301A—Biomedical Scientific Service." The Secretary is authorized to establish a Senior Biomedical Scientific Service, outside the competitive civil service, whose members are to be appointed based on their distinction and achievement in biomedical research or clinical research evaluation. Provisions are made for enhanced compensation rates and for continuity of service for purposes of retirement from the Public Health Service Corps.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman.

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301. * * *

BIOMEDICAL SCIENTIFIC SERVICE

SEC. 301A. (a) ESTABLISHMENT.—The Secretary is authorized to establish a Senior Biomedical Scientific Service (hereinafter in this section referred to as the "Service").

(b) MEMBERSHIP.—

(1) CIVIL SERVICE.—Individuals chosen to serve in the Service shall not be a part of the competitive service established under chapter 33 of subpart B of part I of title 5, United States Code.

(2) APPOINTMENT.—A person may be appointed to the Service by the Secretary based solely on that person's distinction and achievement in the fields of biomedical research or clinical research evaluation.

(c) DUTIES.—Members of the Service shall be assigned to duties that require expertise in biomedical research, behavioral research, or clinical research evaluation, and may also be assigned to supervise other scientists in carrying out the activities described in this subsection.

(d) COMPENSATION.—Individuals selected to serve on the Service staff by the Secretary under subsection (b), shall be compensated at a rate not in excess of 110 percent of the annual rate of pay in effect

for level I of the Executive Salary Schedule established in section 5512 of title 5, United States Code.

(e) Retirement.—For purposes of section 211, the continuous service in the Service of any person who commences such service on termination of service as a commissioned officer in the Public Health Service Corps may be treated as service as a commissioned officer in the Pubic Health Service Corps and shall not be considered as service that is subject to any other retirement system for officers and employees of the Federal government.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

Part A—National Institutes of Health

ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH

Sec. 401. (a) The National Institutes of Health is an agency of the Service.

(b)(1) The following national research institutes are agencies of the National Institutes of Health:

(A) The National Cancer Institute.

(B) The National Heart, Lung, and Blood Institute.

(C) The [National Institute of Diabetes and Digestive and Kidney Diseases] National Institute of Diabetes, Digestive and Kidney Diseases, and Endocrinology.

(D) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(E) The National Institute on Aging.

(F) The National Institute of Allergy and Infectious Diseases.

(G) The National Institute of Child Health and Human Development.

(H) The National Institute of Dental Research.

(I) The National Eye Institute.

(J) The National Institute of Neurological [and Communicative] Disorders and Stroke.

(K) The National Institute of General Medical Sciences.

(L) The National Institute of Environmental Health Sciences.

(M) The National Institute on Deafness and Other Communication Disorders.

* * * * * * *

APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

Sec. 402. (a) The National Institutes of Health shall be headed by the Director of the National Institutes of Health (hereafter in this title referred to as the "Director of NIH") who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

(1) shall be responsible for the overall direction of the National Institutes of Health and for the establishment and im-

plementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes and administrative entities within the National Institutes of Health;

(3) shall assure that research at or supported by the National Institutes of Health is subject to review in accordance with section 492;

(4) for the national research institutes and administrative entities within the National Institutes of Health—

(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, equipment, and other real or personal property, and

(B) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

(5) may secure resources for research conducted by or through the National Institutes of Health;

(6) may without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups *and scientific program advisory committees* as are needed to carry out the requirements of this title and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups:

* * * * * * *

PART B—GENERAL PROVISIONS RESPECTING NATIONAL INSTITUTES

APPOINTMENT AND AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES

SEC. 405. (a) The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.

(b)(1) In carrying out the purposes of section 301 with respect to [the] human diseases or disorders or other aspects of human health [for which the national research institutes were established], the Secretary, acting through the Director of each national research institute *and agency of the National Institutes of Health*—

(A) shall encourage and support research investigations, experiments, demonstrations, and studies in the health sciences related to—

(i) the maintenance of health,

(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

(B) may, subject to the peer review prescribed under section 492(b) and any advisory council review under section 406(a)(3)(A)(i), conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

(C) may conduct and support research training (i) for which fellowship support is not provided under section 487, and (ii) which is not residency training of physicians or other health professionals;

(D) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

(E) may develop, conduct, and support public and professional education and information programs;

(F) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

(G) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

(H) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of $50,000, establish suitable memorials to the donor;

(I) may secure for the institute consultation services and advice of persons from the United States or abroad;

(J) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(K) may accept voluntary and uncompensated services; and

(L) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 2354, title 10, United States Code, shall apply with respect to contracts entered into under this subsection and section 402(b). *For purposes of Federal income, estate, and gift taxes, any gift accepted under subparagraph (H) shall be considered to be a gift or transfer to the United States.*

(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute *and agency of the National Institutes of Health*—

(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after technical and scientific peer review required by regulations under section 492; and

(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

(i) if the direct cost of the grant or cooperative agreement to be made does not exceed $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492, and

(ii) if the direct cost of the grant or cooperative agreement to be made exceeds $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492 and is recommended under section 406(a)(3)(A)(ii) by the advisory council for the national research institute involved.

(c) In carrying out subsection (b), each Director of a national research institute *and agency of the National Institutes of Health*—

(1) shall coordinate, as appropriate, the activities of the institute *or agency* with similar programs of other public and private entities;

(2) shall cooperate with the Directors of the other national research institutes *and agencies* in the development and support of multidisciplinary research and research that involves more than one institute *or agency*; and

[(3) may, with the approval of the advisory council for the institute and the Director of NIH, appoint technical and scientific peer review groups in addition to those appointed under section 402(b)(6).]

(3) may—

(A) with the approval of the advisory council for the institute or agency and the Director of the National Institutes of Health, established technical and scientific peer review groups in addition to those established under section 402(b)(6); and

(B) appoint the members of peer review groups established under subparagraph (A).

ADVISORY COUNCILS

SEC. 406. (a) * * *

(b)(1) Each advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

(2) The ex officio members of an advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established, the Chief Medical Director of the Veterans Administration or the Chief Dental Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including [public health and the] *two individuals who are leaders in the fields of* behavioral or social sciences) relevant to the activities of the national research institute for which the advisory council is established.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule.

(c)–(g) * * *

(h)(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on the date of enactment of the Health Research Extension Act of 1985. After such date—

(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section:

(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.

(2)(A) The National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

(i) appointments to such Board shall be made by the President;

(ii) the terms of office of an appointed member shall be 6 years;

(iii) of the members appointed to the Board not less than five members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors);

(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years:

(v) the ex officio members of the Board *shall be nonvoting members and* shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Chief Medical Director of the Veterans' Administration, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, [and the Assistant Secretary of Defense for Health Affairs] *the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Energy Research of the Department of Energy* (or the designees of such officers): and

(vi) the Board shall meet at least four times each fiscal year.

(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that the advisory council shall meet at least four times each fiscal year.

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AUTHORIZATIONS OF APPROPRIATIONS

SEC. 408. (a) In addition to amounts otherwise authorized to be appropriated under this title for the National Institutes of Health, the following amounts are authorized to be appropriated:

[(1)(A) For the National Cancer Institute (other than its programs under section 412), there are authorized to be appropriated $1,194,000,000 for fiscall year 1986, $1,270,000,000 for fiscal year 1987, and $1,344,000,000 for fiscal year 1988.

[(B) For the programs under section 421, there are authorized to be appropriated $68,000,000 for fiscal year 1986, $74,000,000 for fiscal year 1987, and $80,000,000 for fiscal year 1988.

[(2)(A) For the National Heart, Lung, and Blood Institute (other than its programs under section 419), there are authorized to be appropriated $809,000,000 for fiscal year 1986, $871,000,000 for fiscal year 1987, and $927,000,000 for fiscal year 1988. Of the amount appropriated under this subsection for such fiscal year, not less than 15 percent of such amount shall be reserved for programs respecting diseases of the lung and not less than 15 percent of such amount shall be reserved for programs respecting blood diseases and blood resources.

[(B) For the programs under section 419, there are authorized to be appropriated $82,000,000 for fiscal year 1986, $90,000,000 for fiscal year 1987, and $98,000,000 for fiscal year 1988.]

(1)(A) For the National Cancer Institute (other than its programs under section 412), there are authorized to be appropriated $1,587,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal year 1990 and 1991.

(B) For the programs under section 421, there are authorized to be appropriated $84,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991.

(2)(A) For the National Heart, Lung, and Blood Institute (other than its programs under section 419), there are authorized to be appropriated $1,001,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991. Of the amount appropriated under this subsection for such fiscal year, not less than 15 percent of such amount shall be reserved for programs respecting diseases of the lung and not less than 15 percent of such amount shall be reserved for programs respecting blood diseases and blood resources.

(B) For the programs under section 419, there are authorized to be appropriated $101,000,000 for fiscal year 1989 and such sums as are necessary in each of the fiscal years 1990 and 1991.

* * * * * * *

PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

Subpart 1—National Cancer Institute

SEC. 410. The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of *and rehabilitation from* cancer and the continuing care of cancer patients and the families of cancer patients.

* * * * * * *

SPECIAL AUTHORITIES OF THE DIRECTOR

SEC. 413. (a) The Director of the Institute shall establish an information and education center to collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to cancer patients and their families, physicians and other health professionals, and the general public, information on cancer research, diagnosis, prevention, and treatment (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer). The Director of the Institute may take such action as may be necessary to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(b) The Director of the Institute in carrying out the National Cancer Program—

(1) shall establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for cancer research and set standards of safety and care for persons using such materials;

(2) shall, in consultation with the advisory council for the Institute, support (A) research in the cancer field outside the

United States by highly qualified foreign nationals which can be expected to benefit the American people, (B) collaborative research involving American and foreign participants, and (C) the training of American scientists abroad and foreign scientists in the United States;

(3) shall, in consultation with the advisory council for the Institute, support appropriate programs of education and training (including continuing education and laboratory and clinical research training);

(4) shall encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

(5) may obtain (*in consultation with* the advisory council for the Institute and in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

(6)(A) may, in consultation with the advisory council for the Institute, acquire, construct, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(7) may, in consultation with the advisory council for the Institute, appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments to advise the Director with respect to the Director's functions *and to conduct the technical and scientific peer review required by section 492(b)*;

(8) may, subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), enter into such contracts, leases, cooperative agreements, as may be necessary in the conduct of functions of the Director, with any public agency, or with any person, firm, association, corporation, or educational institution:

(9) shall maintain and operate the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible through the use of information systems accessible to the public, general practitioners, and oncologic investigators, the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country**[**; and**]***;*

(10) may publish or arrange for the publication of information regarding cancer research, prevention, biology and diagnosis, control, and treatment to cancer patients and their families, physicians, and other health professionals, oncologic investigators, and the general public without regard to section 501 of title 44, United States Code; and

[(10)] *(11)*(A) shall, notwithstanding section 405(a), prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council; and (B) [may] *shall* receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the Institute.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (5) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (5) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

9NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

SEC. 414. (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, *control,* and treatment methods for cancer.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

* * * * * * *

INFORMATION AND EDUCATION

SEC. 420. The Director of the Institute shall collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to patients, families of patients, physicians and other health professionals, and the general public, information on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, the maintenance of health to reduce the incidence of such diseases, and on the use of blood and blood products and the management of blood resources. In carrying out this section the Director of the Institute shall place special emphasis upon [—

[(1) the dissemination of information regarding diet and nutrition, environmental pollutants, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arteriosclerosis and other cardiovascular diseases and of pulmonary and blood diseases; and

[(2) the dissemination of information designed to encourage children to adopt healthful habits respecting the risk factors related to the prevention of such diseases.]

the utilization of collaborative efforts with both the public and private sectors to—

(1) increase the awareness and knowledge of health care professionals and the public regarding the prevention of heart and blood vessel, lung, and blood diseases and the utilization of blood resources; and

(2) develop and disseminate to health professionals, patients and patient families, and the public of information designed to encourage adults and children to adopt healthful habits concerning the prevention of such diseases.

NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM

SEC. 421. (a)(1) The National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this subpart referred to as the "Program" may provide for—

(A) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases.

(B) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(C) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including the provision of emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

(D) establishment of programs that will focus and apply scientific and technological efforts involving the biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on the refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of *and rehabilitation from* such diseases;

(E)–(2) * * *

(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—

(1) may, after approval of the advisory council for the Institute, obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of such service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications:

(2) (A) may, in consultation with the advisory council for the Institute, acquire and construct, improve, repair, operate, alter, renovate, and maintain, heart, blood vessel, lung, and blood disease and blood resource laboratories, research, training, and other facilities, equipment, and such other real or personal property as the Director determines necessary:

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities: and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 18[illegible] (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years:

(3) subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, frim, association, corporation, or educational institutions; **[**and**]**

(4) may make grants to public and nonprofit private entities to assist in meeting the cost of the care of patients in hospitals, clinics and related facilities who are participating in research projects**[**.**]**; *and*

(5) shall, in consultation with the advisory council for the Institute, support appropriate programs for education and training (including continuing education and laboratory and clinical research training).

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE, SICKLE CELL ANEMIA, AND BLOOD RESOURCES

SEC. 422. (a)(1) The Director of the Institute may provide, in accordance with subsection (c), for the devlopment of—

(A) ten centers for basic and clincial research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment *and rehabilitation* methods (including methods of providing emergency medical services) for heart and blood vessel diseases;

(B) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment *and rehabilitation* methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children); and

(C) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources.

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INTERAGENCY TECHNICAL COMMITTEE

SEC. 423. [Replealed.]

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Subpart 3—[National Institute of Diabetes and Digestive and Kidney Diseases] *National Insitutie of Diabetes, Digestive and Kidney Diseases and Endocrinology*

PURPOSE OF THE INSTITUTE

SEC. 426. The general purpose of the National Institute of Diabetes and Digestive and Kidney Diseases *National Institute of Diabetes, Digestive and Kidney Diseases, and Endocrinology,* (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases.

* * * * * * *

ADVISORY BOARDS

SEC. 430. (a) The Secretary shall establish in the Institute the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases

Advisory Board (hereafter in this section individually referred to as an "Advisory Board").

(b) Each Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health profesisonals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in the fields of health education, nursing, data systems, public information, and community program development.

(2)(A) The following shall be ex officio members of each Advisory Board:

(i) The Assistant Secretary for Health, the Director of NIH, the Director of the [National Institute of Diabetes and Digestive and Kidney Diseases] *National Institute of Diabetes, Digestive and Kidney Diseases, and Endocrinology,* the Director of the Centers for Disease Control, the Chief Medical Director of the Veterans' Administration, the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officrs).

* * * * * * *

[(k) Each Advisory Board shall expire on September 30, 1988]

[(l)] *(k)* The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Boards established under subsection (a) before the expiration of 90 days after such date. The members of the Boards in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Boards established under subsection (a) for diabetes and digestive diseases, except that at least one-half of the members of the National Diabetes Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall be appointed to the National Diabetes Advisory Board first established under subsection (a).

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[NATIONAL ARTHRITIS AND MUSCULOSKELETAL DISEASES PROGRAM

[SEC. 436. (a) The Director of the Institute, with the advice of the Institute's advisory council, shall prepare and transmit to the Director of NIH a plan for a national arthritis and musculoskeletal diseases program to expand, intensify, and coordinate the activities of the institute respecting arthritis and musculoskeletal diseases. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of NIH.

[(b) Activities under the national arthritis and musculoskeletal diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilties respecting arthritis and musculoskeletal diseases, and shall, at least, provide for—

[(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis and musculoskeletal diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis and musculoskeletal diseases:

[(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation, and prevention of arthritis and musculoskeletal diseases:

[(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures; and

[(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields.

[(c) The Director of the Institute shall carry out the national arthritis and musculoskeletal diseases program in accordance with the plan prepared under subsection (a) and any revision sof such plan made under such subsection.]

NATIONAL ARTHRITIS AND MUSCULOSKELETAL DISEASES PROGRAMS

SEC. 436. (a) Plan.—The Director of the Institute, with the advice of the Institute's advisory council, shall prepare and transmit to the Director of the National Institutes of Health a plan for a national arthritis, musculoskeletal and skin diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis, musculoskeletal and skin diseases. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of the National Institutes of Health.

(b) ACTIVITIES.—Activities under the national arthritis, musculoskeletal and skin diseases program shall be coorinated with the

other national research institutes to the extent that such institutes have responsibilities respecting arthritis, musculoskeletal and skin diseases, and shall, at least, provide for—

(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis, musculoskeletal and skin diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis, musculoskeletal and skin diseases;

(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation, and prevention of arthritis, musculoskeletal and skin diseases;

(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures; and

(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields.

(c) ADMINISTRATION.—The Director of the Institute shall carry out the national arthritis, musculoskeletal and skin diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.

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MULTIPURPOSE ARTHRITIS AND MUSCULOSKELETAL DISEASES CENTERS

SEC. 441. (a) The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis and musculoskeletal diseases. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Each center assisted under this section shall—

(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

(2) conduct—

(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of *and rehabilitation from* arthritis and musculoskeletal diseases and complications resulting from arthritis and musculoskeletal diseases, including research into implantable biomaterials and biomechanical and other orthopedic procedures;

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Subpart 5—National Institute on Aging

PURPOSE OF THE INSTITUTE

Secs. 443–445. * * *

CENTERS OF GERIATRIC RESEARCH AND TRAINING

Sec. 445A. (a) Grants.—The Director of the Institute shall enter into cooperative agreements with, and make grants to, public and private nonprofit entities for the development or expansion of centers of excellence in geriatric research and training.

(b) Duties of Centers.—Each center developed or expanded under this section shall—

(1) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director; and

(2) conduct—

(A) research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging; and

(B) programs to develop individuals capable of conducting research concerning aging and concerning such diseases, disorders, and complications.

(c) Limitations.—In making cooperative agreements and grants under this section for the development or expansion of centers, the Director of the Institute shall provide that such centers are—

(1) geographically distributed throughout the United States; and

(2) located at entities with proven research capabilities and emerging centers of excellence.

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Subpart 10—National Institute of Neurological [and Communicative] Disorders and Stroke

PURPOSE OF THE INSTITUTE

Sec. 457. The general purpose of the National Institute of Neurological [and Communicative] Disorders and Stroke (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to neurological disease and [disorder, stroke, and disorders of human communication] *disorder and stroke.*

CENTERS FOR THE STUDY OF DEAFNESS AND OTHER COMMUNICATIVE DISORDERS

Sec. 457A. (a) Grants.—

(1) In general.—The Director of the Institute may enter into cooperative agreements with, and make grants to, public or private nonprofit entities to pay all or part of the cost of planning, establishing, strengthening, or providing basic operating sup-

port for eight new or existing centers for disorders of hearing and communication diseases.

(2) Policies.—A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of the National Institutes of Health after consultation with the advisory council of the Institute.

(b) Use of Funds.—Each center provided with funds, or otherwise asssisted under this section, shall conduct—

(1) basic and clinical research into the cause diagnosis, early detection, prevention, control and treatment of, and rehabilitation from, disorders of hearing and other communication processes and complications resulting from such disorders;

(2) training programs for physicians, scientists, and other health and allied health professionals;

(3) information and continuing education programs for physicians and other health and allied health professionals who will provide care for patients with disorders of hearing or other communication processes; and

(4) programs for the dissemination to the general public of information on the importance of prevention and early detection of disorders of hearing and other communication processes.

(c) Stipends.—A center provided with funds or otherwise assisted subsection (a), may use funds provided under such subsection to provide stipends for health professionals enrolled in training programs described in subsection (b)(2).

(d) Demonstration Programs.—Each center provided with funds or otherwise assisted subsection (a), may conduct demonstration programs—

(1) to establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals at risk of developing disorders of hearing or other communication processes; and

(2) to disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping.

(e) Distribution of Centers.—The Director of the Institute shall, to the extent practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of the elderly, and of children affected by disorders of hearing or other communication processes.

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Subpart 13—National Institute on Deafness and Other Communication Disorders

PURPOSE OF THE INSTITUTE

Sec. 464. The general purpose of the National Institute on Deafness and Other Communication Disorders (hereafter referred to in this subpart as the "Institute") is the conduct and support of research and training, the dissemination of health information, and other programs with respect to disorders of hearing and other com-

munication processes, including diseases affecting hearing, balance, voice, speech, taste, and smell.

NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS PROGRAM

Sec. 464A. (a) Establishment.—

(1) In general.—The Director of the Institute, with the advice of the Institute's advisory council, shall establish a National Deafness and Other Comunication Disorders Program (hereafter in this section referred to as the "Program").

(2) Preparation of plan.—The Director of the Institute shall, with respect to the Program, prepare and transmit to the Director of the National Institutes of Health a plan to initiate, expand, intensify and coordinate the activities of the Institute respecting disorders of hearing, balance, voice, speech, taste, and smell.

(3) Contents of plan.—The plan prepared under paragraph (1) shall include such comments and recommendations as the Director of the Institute determines appropriate.

(4) Revision of plan.—The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Director of the National Institutes of Health.

(b) Activities.—Activities under the Program shall be coordinated with other national research institutes to the extent that such institutes have responsibilities respecting disorders of hearing or other communication processes and shall, at least, provide for—

(1) investigation into the etiology, pathology, detection, treatment, and prevention of all forms of disorders of hearing and other communication processes, primarily through the support of basic research in such areas as epidemiolgy, immunology, physiology, genetics, anatomy, biochemistry, microbiology, bioengineering, pharmacology, otolaryngology, audiology, speech pathology, molecular biology and the neurosciences, and any other scientific disciplines which can contribute important knowledge to the understanding and elimination of disorders of hearing and other communication processes;

(2) research into the evaluation of techniques. drugs, and devices (including hearing aids, implanted auditory prosthetic devices and artificial speech aids for protection as well as assistance for these patients used in diagnosis, treatment, rehabilitation and prevention of disorders of hearing and other communication processes;

(3) research into early detection and diagnosis of hearing loss and speech disturbances (including stuttering in children) and research into preventing the effects of such disorders on learning and learning disabilities with extension of programs for appropriate referral and rehabilitation;

(4) research into the detection, treatment, and prevention of disorders of hearing and other communication processes in the growing elderly population with extension of rehabilitative programs to ensure continued effective communication skills in such population; and

(5) research to refine the basic understanding of the effects of environmental agents that influence hearing or other communication processes.

DATA SYSTEM AND INFORMATION CLEARINGHOUSE

SEC. 464B. (a) DATA SYSTEM.—The Director of the Institute shall establish a National Deafness and Other Communication Disorders Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with disorders of hearing or other communication processes, including where possible, data involving general populations for the purpose of identifying individuals at risk of developing such disorders.

(b) INFORMATION CLEARINGHOUSE.—The Director of the Institute shall establish a National Deafness and Other Communication Disorders Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of disorders of hearing and other communication processes by health professionals, patients, industry and the public.

MULTIPURPOSE DEAFNESS AND OTHER COMMUNICATION DISORDERS CENTER

SEC. 466C. (a) DEVELOPMENT.—

(1) In general.—The Director the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including care required for research) of new and existing centers for studies of disorders of hearing and other communication processes.

(2) DEFINITION.—For purposes of this section, the term 'modernization' means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) REQUIREMENTS OF CENTERS.—Each center assisted under this section shall—

(1) use the facilities of a single institution or a consortium of cooperating institutions; and

(2) meet such qualifications as may be prescribed by the Secretary.

(c) ACTIVITIES OF CENTERS.—Each center assisted under this section shall conduct—

(1) basic and clinical research into the cause diagnosis, early detection, prevention, control and treatment of disorders of hearing and other communication processes and complications resulting from such disorders, including research into rehabilitative aids, implantable biomaterials, auditory speech processors, speech production devices, and other otolaryngologic procedures;

(2) training programs for physicians, scientists, and other health and allied health professionals;

(3) information and continuing education programs for physicians and other health and allied health professionals who will

provide care for patients with disorders of hearing or other communication processes; and

(4) programs for the dissemination to the general public of information—

(A) on the importance of early detection of disorders of hearing and other communication processes, of seeking prompt treatment, rehabilitation, and of the following an appropriate regimen; and

(B) on the importance of avoiding exposure to noise and other environmental toxic agents that may affect disorders of hearing or other communication processes.

(d) STIPENDS.—A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in subsection (c)(2).

(e) PROGRAMS.—Each center assisted under this section may conduct programs—

(1) to establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals at risk of developing disorders of hearing or other communication processes; and

(2) to disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping.

(f) DISTRIBUTION OF CENTERS.—

(1) GEOGRAPHICAL LOCATION.—The Director of the Institute shall, to the extent practicable, provide for an equitable geographical distribution of centers assisted under this section.

(2) CHILDREN AND ELDERLY INDIVIDUALS.—The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of the elderly, and of children (particularly with respect to their education and training), affected by disorders of hearing or other communication processes.

(g) PERIOD OF SUPPORT.—

(1) IN GENERAL.—Support of a center under this section may be for a period not to exceed 7 years.

(2) EXTENTION OF PERIOD.—The period referred to in paragraph (1) may be extended by the Director of the Institute for one or more additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director, with the advice of the Institute's advisory council, if such group has recommended to the Director that such period should be extended.

AUTHORIZATION OF APPROPRIATIONS

SEC. 464D. For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as are determined necessary by the Secretary.

Part D.—National Library of Medicine

Subpart 1—General Provisions

PURPOSE, ESTABLISHMENT, AND FUNCTIONS OF THE NATIONAL LIBRARY OF MEDICINE

Sec. 465. * * *

BOARD OF REGENTS

Sec. 466. (a)(1)(A) The Board of Regents of the National Library of Medicine consists of ex officio members and [ten members appointed by the Secretary] *13 members appointed by the President.*

* * * * * * *

Subpart 2—Financial Assistance

AUTHORIZATION OF APPROPRIATIONS

Sec. 469. [For the purpose of grants and contracts under sections 472, 473, 474, 475, and 476, there are authorized to be appropriated $12,000,000 for fiscal year 1986, $13,000,000, for fiscal year 1987, and $14,000,000 for fiscal year 1988.] *For the purpose of grants and contracts under sections 472 through 476, there are authorized to be appropriated $14,000,000 for fiscal year 1989 and such sums as are necessary for each of the fiscal years 1990 and 1991.* Funds appropriated under this section shall remain available for such purposes until the end of the fiscal year immediately following the fiscal year for which they were appropriated.

* * * * * * *

ASSISTANCE FOR SPECIAL SCIENTIFIC PROJECTS, AND FOR RESEARCH AND DEVELOPMENT IN MEDICAL LIBRARY SCIENCE AND RELATED FIELDS

Sec. 473. (a) The Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientist for the compilation of existing, or the writing of original contributions relating to scientific, social, or cultural advancements in sciences related to health. In making such grants, the Secretary shall make appropriate arrangements under which the facilities of the Library and the facilities of libraries of public and private nonprofit institutions of higher learning may be made available in connection with the project for which such grants are made.

(b) The Secretary shall make grants to appropriate public or private non-profit institutions and enter into contracts with appropriate persons, for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems, and equipment, for processing, storing, retrieving, and distributing information pertaining to sciences related to health.

(c) The Secretary shall make grants to appropriate public or private nonprofit institutions for the purpose of carrying out projects in the research, development, and demonstration of new educational

technologies. Such projects shall assist in the training of health professions students, and enhance and improve the research and teaching capabilities of health professionals. Funding may support projects including those concerning computer-assisted teaching and testing of clinical competence at health professions and research institutions, the effective transfer of new information from research laboratories to appropriate clinical applications, the expansion of the laboratory and clinical uses of computer-stored research databases, and the testing of new technologies for training health care professionals in non-traditional settings.

GRANTS FOR ESTABLISHING, EXPANDING, AND IMPROVING THE BASIC RESOURCES OF MEDICAL LIBRARIES AND RELATED INSTRUMENTALITIES

SEC. 474. (a) The Secretary shall make grants of money, materials, or both, to public or private nonprofit medical libraries and related scientific communication instrumentalities for the purpose of establishing, expanding, and improving their basic medical library or related resources. A grant under this subsection may be used for—

(1) the acquisition of books, journals, photographs, motion picture and other films, and other similar materials;

(2) cataloging, binding, and other services and procedures for processing library resource materials for use by those who are served by the library or related instrumentality;

(3) the acquisition of duplication devices, facsimile equipment, film projectors, recording equipment, and other equipment to facilitate the use of the resources of the library or related instrumentality by those who are served by it; **[**and**]**

(4) the introduction of new technologies in medical librarianship**[**.**]***; and*

(5) the acquisition, construction, or renovation of facilities.

(b)(1) The amount of any grant under this section to any medical library or related instrumentality shall be determined by the Secretary on the basis of the scope of library or related services provided by such library or instrumentality in relation to the population and purposes served by it. In making a determination of the scope of services served by any medical library or related instrumentality, the Secretary shall take into account—

(A) the number of graduate and undergradute students making use of the resources of such library or instrumentality;

(B) the number of physicians and other practitioners in the sciences related to health utilizing the resources of such library or instrumentality;

(C) the type of supportive staffs, if any, available to such library or instrumentality;

(D) the type, size, and qualifications of the faculty of any school with which such library or instrumentality is affiliated;

(E) the staff of any hospital or hospitals or of any clinic or clinics with which such library or instrumentality is affiliated; and

(F) the geographic area served by such library or instrumentality and the availability within such area of medical library or related services provided by other libraries or related instrumentalities.

(2) Grants to such medical libraries or related instrumentalities under this section shall be in such amounts as the Secretary may by regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which grants are provided[, except that in no case shall any grant under this section to a medical library or related instrumentality for any fiscal year exceed $500,000].

GRANTS AND CONTRACTS FOR ESTABLISHMENT OF REGIONAL MEDICAL LIBRARIES

SEC. 475. (a) The Secretary, with the advice of the Board, shall make grants to and enter into contracts with existing public or private nonprofit medical libraries so as to enable each of them to serve as the regional medical library for the geographical area in which it is located.

(b) The uses for which grants and contracts under this section may be employed include the—

(1) acquisition of books, journals, and other similar materials;

(2) cataloging, binding, and other procedures for processing library resource materials for use by those who are served by the library;

(3) acquisition of duplicating devices and other equipment to facilitate the use of the resources of the library by those who are served by it;

(4) acquisition of mechanisms and employment of personnel for the speedy transmission of materials from the regional library to local libraries in the geographic area served by the regional library: [and]

(5) planning for services and activities under this section [.] *; and*

(6) the acquisition, construction, or renovation of facilities.

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PART E—OTHER AGENCIES OF NIH

Subpart 1—Division of Research Resources

* * * * * * *

CENTERS FOR BIOMEDICAL ETHICS

SEC. 481A. (a) IN GENERAL.—The Director of the Division of Research Resources shall enter into cooperative agreements and make grants to public and private nonprofit entities for the development or expansion of no less than five centers of excellence in biomedical and behavioral research ethics.

(b) DUTIES.—Each center shall examine, analyze, issue reports and recommendations, gather, store, and disseminate information regarding the ethical issues and principles resulting from—

(1) the conduct of biomedical and behavioral research;

(2) the delivery of health care services and experimental therapy and procedures; and

(3) the use of new technologies in the provision of health care.

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Subpart 3—National Center for Nursing Research

PURPOSE OF THE CENTER

SEC. 483. * * *

SPECIFIC AUTHORITIES

[SEC. 484. To carry out section 483, the Director of the Center may provide research training and instruction and establish, in the Center and other nonprofit institutions, research traineeships and fellowships in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses. The Director of the Center may provide individuals receiving such training and instruction or such traineeships or fellowships with such stipends and allowances (including amounts for travel and subsistence and dependency allowances) as the Director determines necessary. The Director may make grants to nonprofit institutions to provide such training and instruction and traineeships and fellowships.]

SEC. 484. To carry out section 483, the Director of the Center may—

(1) provide research training and instruction and establish, in the Center and other nonprofit institutions, research traineeships and fellowships in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses;

(2) provide individuals receiving such training and instruction under paragraph (1) or such traineeships or fellowships with such stipends and allowances (including amounts for travel and subsistence and dependency allowances) as the Director determines necessary;

(3) make grants to nonprofit institutions to provide training and instruction and traineeships and fellowships under paragraph (1);

(4) enter into cooperative agreements with, and make grants to, public and private nonprofit entities to fund all or part of research and demonstration projects that may include projects for research concerning—

(A) innovative models of nursing care;

(B) problems relating to the national nursing shortage; and

(C) the quality of the nursing role with regard to patient care; and

(5) in consultation with the Advisory Council established under section 485, make grants for the acquisition, construction, or renovation of facilities.

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Subpart 4—National Center for Medical Rehabilitation Research

PURPOSE OF THE CENTER

SEC. 486A. The general purpose of the National Center for Medical Rehabilitation Research (hereafter in this subpart referred to as the 'Center') is the conduct and support of biomedical and related research and research training, the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, or other physiologic systems (hereafter in this subpart referred to as "medical rehabilitation").

APPOINTMENT OF THE DIRECTOR

SEC. 486B. The Director of the Center shall be appointed by the Secretary and shall report directly to the Director of the National Institutes of Health.

SPECIFIC AUTHORITIES

SEC. 486C. In carrying out the purpose described in section 486A, the Director of the Center may—

(1) make grants and enter into cooperative agreements and contracts;

(2) provide for clinical trials with respect to medical rehabilitation;

(3) provide for research with respect to model systems of medical rehabilitation;

(4) coordinate the activities of the Center with similar activities of other agencies of the Federal Government, including the other agencies of the National Institutes of Health, and with similar activities of other public entities and of private entities;

(5) support multidisciplinary medical rehabilitation research conducted or supported by more than one such agency;

(6) with the approval of the Director of the National Institutes of Health and the advisory council established under section 465F, appoint technical and scientific peer review groups in addition to any such groups appointed under section 402(b)(6); and

(7) support medical rehabilitation research and training centers.

RESEARCH PLAN

SEC. 486D. (a) DEVELOPMENT.—After consultation with the Director of the Center, the advisory council established under section 486F, and the coordinating committee established under section 486E, the Director of the National Institutes of Health shall develop *a comprehensive plan for the conduct and support of medical rehabilitation research .*

(b) CONTENTS.—*The plan shall identify priorities with respect to such research and shall provide for the coordination of such research conducted or supported by the agencies of the National Institutes of Health.*

(c) REVISION.—*The Director of the National Institutes of Health shall (after consultation with the Director of the Center and with such advisory council and such coordinating committee) revise the plan as appropriate.*

COORDINATING COMMITTEE

SEC. 486E. (a) ESTABLISHMENT.—*The Director of the National Institutes of Health shall establish a committee to be known as the Medical Rehabilitation Coordinating Committee (hereinafter in this subpart referred to as the "Coordinating Committee").*

(b) COMPOSITION.—*The Coordinating Committee shall be composed of the directors of the National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Child Health and Human Development, the National Institute of Neurological and Communicative Disorders and Stroke, and of such other national research institutes as the Director of the National Institutes of Health determined to be appropriate.*

(c) DUTIES.—*The Coordinating Committee shall make recommendations to the Director of National Institutes of Health and the Director of the Center with respect to the content of the plan required in section 486D and with respect to the activities of the Center that are carried out in conjunction with other agencies of the National Institutes of Health.*

ADVISORY COUNCIL

SEC. 486FG. (a) ESTABLISHMENT.—*The Director of the National Institutes of Health shall establish a council to be known as the Medical Rehabilitation Advisory Council (hereinafter in this section referred to as the "Advisory Council").*

"(b) DUTIES.—*The Advisory Council shall advise, assist, consult with, and make recommendations to the Director of the National Institutes of Health and the Director of the Center on matters relating to the activities carried out by and through the Center and the policies respecting such activities, including recommendations with respect to the plan required in section 486D.*

(c) MEMBERSHIP.—

(1) IN GENERAL.—*The Director of the National Institutes of Health shall appoint to the Advisory Council 18 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, 12 shall be representatives of health and scientific disciplines with respect to medical rehabilitation and 6 shall be individual representing the interests of individuals undergoing, or in need of, medical rehabilitation.*

(2) EX OFFICIO MEMBERS.—*The following officials shall serve as ex officio members of the Advisory Council:*

(A) The Director of the National Institutes of Health.

(B) The Director of the Center.

(C) The Director of the National Institute on Aging.

(D) The Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(E) The Director of the National Institute of Child Health and Human Development.

(F) The Director of the National Institute of Neurological and Communicative Disorders and Stroke.

(G) The Assistant Secretary for Special Education and Rehabilitiative Services.

(H) The Assistant Secretary of Defense (Health Affairs).

(I) The Chief Medical Director of the Veterans' Administration.

(d) CHAIRPERSON.—The Director of the National Institutes of Health shall designate a chairperson from among the members of the Advisory Council.

(e) CONSTRUCTION.—Except as inconsistent with, or inapplicable to, this section, the provisions of section 406 shall apply to the advisory council established under this section in the same manner as such provisions apply to any advisory council established under section 406.

PART F—AWARDS AND TRAINING

NATIONAL RESEARCH SERVICE AWARDS

SEC. 487. (a)(1) The Secretary shall—

(A) provide National Research Service Awards for—

(i) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health and Administration are directed;

(ii) training at the National Institutes of Health and at the Administration of individuals to undertake such research;

(iii) biomedical and behavioral research and health services research (including research in primary medical care) at public and nonprofit private entities; and

(iv) pre-doctoral and post-doctoral training at public and private institutions of individuals to undertake biomedical and behavioral research; and

(B) make grants to public and nonprofit private institutions to enable such institutions to make National Research Service Awards for research (and training to undertake biomedical and behavioral research) in the matters described in subparagraph (A)(i) to individuals selected by such institutions.

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be considered to include the institutes, agencies, divisions, and bureaus included in the National Institutes of Health or under the Administration, as the case may be.

(2) National Research Service Awards may not be used to support residency training of physicians and other health professionals.

(3) In awarding National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(4) The Secretary, acting through the Director of the National Institutes of Heatlh, shall assure that support is provided for multidisciplinary research training in disciplines not readily identified with existing categorical institutes.

(b)–(c) * * *

(d) [There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such awards $244,000,000 for fiscal year 1986, $260,000,000 for fiscal year 1987, and $275,000,000 for fiscal year 1988.] *There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such awards $350,000,000 for fiscal year 1989 and such sums as are necessary for each of the fiscal years 1990 and 1991.* Of the amounts appropriated under this subsection—

(1) not less than 15 percent shall be made available for payments under National Research Service Awards provided by the Secretary under subsection (a)(1)(A);

(2) not less than 50 percent shall be made available for grants under subsection (a)(1)(B) for National Research Service Awards;

(3) one-half of one percent shall be made available for payments under National Research Service Awards which (A) are made to individuals affiliated with entities which have received grants or contracts under section 780, 784, or 786, and (B) are for research in primary medical care; and one-half of one percent shall be made available for payments under National Research Service Awards made for health services research by the National Center for Health Services Research and Health Care Technology Assessment under section 304(a)(3); and

(4) not more than 4 percent may be obligated for National Research Service Awards for periods of three months or less.

* * * * * * *

PART G—GENERAL PROVISIONS

* * * * * * *

PEER REVIEW REQUIREMENTS

SEC. 492. (a)(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

(A) applications made for grants and cooperative agreements under this Act for biomedical and behavioral research; and

(B) applications made for biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

(2) Regulations promulgated under paragraph (1) shall require that the review of applications made for grants, contracts, and cooperative agreements required by the regulations be conducted—

(A) to the extent practical, *and congruent with changing review need,* in a manner consistent with the system for technical and scientific peer review applicable on the date of the date of enactment of the Health Research Extension Act of 1985 to grants under this Act for biomedical and behavioral research, and

(B) to the extent practical, by technical and scientific peer review groups performing such review on or before such date,

and shall authorize such review to be conducted by groups appointed under sections 402(b)(6) and 405(c)(3).

(b) The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

(1) the reviewing entity be provided a written description of the research to be reviewed, and

(2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity,

and shall authorize such review to be conducted by groups appointed under sections 402(b)(6) and 405(c)(3)*; except as provided in section 413(b)(7).*

* * * * * * *

FETAL RESEARCH

Sec. 498. (a)–(b) * * *

[(c)(1) The Biomedical Ethics Advisory Committee appointed under section 381 shall conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk standard published in section 46.102(g) of such part 46 (or any successor to such regulations). The Committee shall complete the study and report its findings to the Biomedical Ethics Board established under section 381 not later than the expiration of thirty months after the date of enactment of this section. The report shall include the recommendtions, if any, of the Committee on the advisability of the authority for such a waiver and the circumstances under which such a waiver might be granted. The Biomedical Ethics Board shall transmit the report to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate.

[(2) During the thirty-six-month period beginning on the date of enactment of this section, the Secretary may not grant (under section 46.211 of part 45 of title 46 of the Code of Federal Regulations or any successor to such section) a modification or waiver for fetal research.

[(3) Effective October 31, 1988, paragraph (2) is repealed.]

(c)(1) Not later than 1 year after the date of enactment of this subsection, the Secretary shall appoint an Ethics Advisory Board that

shall advise the Secretary and biomedical researchers regarding research on fetal therapy and on research involving human fetuses.

(2) The Board shall consist of 15 members to be appointed as follows:

(A) Seven members shall be appointed by the Secretary who shall be distinguished in biomedical or behavioral research. Of such members, four shall have had experience with research involving human fetuses, and three shall have had experience in research involving children.

(B) Three members shall be appointed by the Secretary who shall be distinguished in the practice of medicine, or otherwise distinguished in the provision of health care. Of such members, one shall have expertise in obstetrics, and one shall have expertise in neonatology.

(C) Four members shall be appointed by the Secretary who shall be distinguished in the fields of ethics, theology, and law.

(D) One member shall be appointed by the Secretary who shall be representative of citizens with an interest in biomedical ethics but who shall possess no specific expertise in such.

(3) The term of office of each member of the Board shall be 3 years, except that any such member appointed to fill a vacancy occurring prior to the expiration of the term for which such members predecessor was appointed shall be appointed for the remainder of such term. The terms of the members of the Board shall be staggered by the Secretary so as to establish a rotating membership.

(4)(A) Not later than 90 days after the date of enactment of this subsection, the Secretary shall issue a contract proposal, to which the National Academy of Sciences shall be invited to apply, for a grant or contract to examine the scientific, ethical, and funding issues surrounding the conduct of research on fetal therapy and involving human fetuses.

(B) As part of an examination conducted under subparagraph (A), the recipient shall review the regulations contained in section 46.208 of title 45, Code of Federal Regulations, and prepare and submit to the Secretary an analysis of the biomedical and ethical implications of exercising a waiver of the risk standard as contained in section 46.102(g) of title 45, Code of Federal Regulations. Not later than 18 months after the date of enactment of this subsection, the Secretary shall deliver a copy of such report to the Ethic Advisory Board, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate.

(5) During the 2-year period beginning on the date of enactment of this subsection, the Secretary may not grant (under section 46.211 of title 45, Code of Federal Regulations or any successor to such section) a modification or waiver for fetal research.

CONSTRUCTION OF TITLE

SEC. 499. This title shall not be construed as limiting (1) the functions or authority of the Secretary under section 301 or of any officer or agency of the United States, relating to the study, prevention, diagnosis, and treatment of any disease for which a separate national research institute is established under this title, or (2) the expenditure of any funds therefor.

PART H—BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

GRANTS FOR CONSTRUCTION

SEC. 499A. The Director of the National Institutes of Health, through the Director of Research Resources (hereinafter in this part referred to as the "Director"), is authorized to award grants to public and nonprofit private institutions to expand remodel, renovate, or alter existing research facilities or construct new research facilities pursuant to this part. Applications for grants shall be evaluated on the basis of merit as provided in section 499H.

TECHNICAL REVIEW BOARD ON BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

SEC. 499B. (a) ESTABLISHMENT.—

(1) IN GENERAL.—There is established in the Division of Research Resources of the National Institutes of Health a Technical Review Board on Biomedical and Behavioral Research Facilities (hereinafter referred to in this part as the "Board") to advise the Director and the Advisory Council established pursuant to section 480 (hereinafter in this part referred to as the "Advisory Council") on matters concerning the construction of facilities, and to conduct the peer review of applications received for this part.

(2) MEMBERSHIP.—The Board shall be appointed by the Director, and consist of not fewer than—

(A) 12 members appointed without regard to the civil service laws; and

(B) an official of the National Science Foundation designated by the National Science Board.

(3) FACTORS FOR APPOINTMENTS.—In selecting persons for appointment to the Board under paragraph (2), the Director shall consider factors such as—

(A) experience in the planning, construction, financing, and administration of institutions engaged in the conduct of research in the biomedical or behavioral sciences;

(B) familiarity with the need for biomedical or behavioral research facilities;

(C) familiarity with the need for dentistry, nursing, pharmacy, and allied health professions research facilities; and

(D) experience with emerging centers of excellence as defined in section 499C(d)(2).

(b) DUTIES.—The Board shall—

(1) advise and assist the Director and the Advisory Council in the preparation of general regulations and with respect to policy matters arising in the administration of this part;

(2) make recommendations to the Director and the Advisory Council concerning—

(A) merit review of applications for grants; and

(B) the amount that should be granted to each applicant whose application, in its opinion, should be approved; and

(3) prepare an annual report for the Advisory Council, which shall be available to the public, that—

(A) describes the activities of the Board in the fiscal year for which the report is made;

(B) describes and evaluates the progress made in such fiscal year in meeting the facilities needs for the biomedical research community;

(C) summarizes and analyzes expenditures made by the Federal government for such activities;

(D) reviews the approved but unfunded applications for grants; and

(E) contains the recommendations of the Board for any changes in the implementation of this part.

(c) TERMS.—

(1) TERMS.—Each appointed member of the Board shall hold office for a term of 4 years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of such term.

(2) STAGGERED TERMS.—Of the initial members appointed to the Board—

(A) three shall hold office for a term of 3 years;

(B) three shall hold office for a term of 2 years; and

(C) three shall hold office for a term of 1 year;

as designated by the Director at the time of appointment.

(3) REAPPOINTMENT.—No member shall be eligible for reappointment until a year has elapsed since the end of such member's preceding term.

(d) COMPENSATION.—Members of the Board who are not officers or employees of the United States shall receive for each day the members are engaged in the performance of the functions of the Board compensation at the same rate received by members of other national advisory councils established under this title.

(e) USE OF MEMBERS.—The Director is authorized to use the services of any member or members of the Board, and where appropriate, any member or members of any other national advisory council established pursuant to this title, in connection with matters related to the administration of this part, for such periods, in addition to conference periods, as the Director may determine. The Director shall make appropriate provision for consultation between and coordination of the work of the Board and the Advisory Council, with respect to matters bearing on the purposes and administration of this part.

(f) ADMINISTRATION.—The administration of the Board's functions shall be the responsibility of the Director and shall be carried out in the same manner as the administration of the functions of the Advisory Council.

(g) BOARD ACTIVITIES.—

(1) IN GENERAL.—In carrying out its functions under this part, the Board may establish subcommittees, convene workshops and conferences, and collect data as the Board considers appropriate.

(2) SUBCOMMITTEES.—Subcommittees formed under paragraph (1) may be composed of Board members and nonmember consult-

ants with expertise in the particular area to be address by the subcommittees. The subcommittee may hold meetings as determined necessary to enable the subcommittee to carry out its activities.

APPLICATION AND SELECTION FOR GRANTS

SEC. 499C. (a) SUBMISSION.—Applicants for grants under this part shall be submitted no less frequently than annually to the Director by public and nonprofit private institutions.

(b) AWARDING OF GRANTS.—A grant under this part may be awarded by the Director if—

(1) the applicant institution is determined by the Director to be competent to engage in the type of research for which the proposed facility is to be constructed;

(2) the applicant institution meets the eligibility conditions established by the Director;

(3) the application contains or is supported by the reasonable assurances that—

(A) for not less than 20 years after completion of construction, the facility will be used for the purposes of research for which it is to be constructed;

(B) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility; and

(C) sufficient funds will be available, when construction is completed, for effective use of the facility for the research for which it is being constructed; and

(4) the proposed construction will expand the applicant's capacity for research, or is necessary to improve or maintain the quality of the applicant's research.

A grant under this part may be made only if the application therefor is recommended for approval by the Advisory Council

(c) ELIGIBILITY CONDITIONS.—Within such aggregate monetary limit as the Director may prescribe, applications that, solely by reason of the inability of the applicants to give the assurance required by subsection (b)(2), fail to meet the requirements for application set forth in this section may be approved on condition that the applicants give the assurance required by such paragraph within a reasonable time and on such other reasonable terms and conditions as the Director may determine.

(d) AWARDING GRANTS.—

(1) IN GENERAL.—In acting on applications for grants under this part, the Director shall take into consideration—

(A) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding capacity for biomedical or behavioral research and in improving the quality of such research;

(B) the quality of research or training, or both, to be carried out in the facilities involved;

(C) the need of the institution for such facilities in order to maintain or expand the institutions' research and training mission;

(D) the congruence of the research activities to be carried out within the facility with the research and investigator manpower needs of the United States; and

(E) the age and condition of existing research facilities and equipment.

(2) INSTITUTIONS OF EMERGING EXCELLENCE.—

(A) IN GENERAL.—In addition to paragraph (1), the Director shall consider other criteria for the awarding of grants for the construction of research facilities to eligible institutions that demonstrate emerging excellence in biomedical or behavioral research.

(B) ELIGIBILITY.—To be eligible for a grant under this paragraph, an institution shall—

(i) have a plan for research or training advancement and the ability to carry out the plan; and

(ii)(I) carry out research and research training programs that have a special relevance to a problem, concern, or unmet need of the United States;

(II) have already demonstrated a commitment to enhancing and expanding their research productivity; or

(III) have been productive in research or research development and training in settings where significant barriers to institutional development have been created by—

(aa) The underrepresentation of minorities in health science careers;

(bb) the health status deficit of a large segment of the population; or

(cc) a regional deficit in health care technology, services, or research resources that can adversely affect health status in the future.

AMOUNT OF GRANT; PAYMENTS

SEC. 499D. (a) AMOUNT.—The amount of any grant awarded under this part shall be determined by the Director, except that such amount may not exceed—

(1) 50 percent of the necessary cost of the construction of a proposed facility as determined by the Director; or

(2) in the case of a multipurpose facility, 50 percent of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

(b) RESERVATION OF AMOUNTS.—On approval of any application for a grant under this part, the Director shall reserve, from any appropriation available therefor, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with construction progress, as the Director may determine. The Director's reservation of any amount under this subsection may be amended by the Director, either on approval of an amendment of the application or on revision of the estimated cost of construction of the facility.

(c) Exclusion of Certain Costs.—In determining the amount of any grant under this part, there shall be excluded from the cost of construction an amount equal to the sum of—

(1) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to be financed in part by grant authorized under this part; and

(2) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.

(d) Waiver of Limitations.—The limitations imposed by subsection (a) may be waived at the discretion of the Director for institutions described in section 499C(d)(2).

RECAPTURE OF PAYMENTS

Sec. 499E. If, within 20 years after the completion of construction for which a grant has been awarded under this part—

(1) the applicant or other owner of the facility shall cease to be a public or nonprofit private institution; or

(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so);

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by agreement of the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

NONINTERFERENCE WITH ADMINISTRATION OF INSTITUTIONS

Sec. 499F. Except as otherwise specifically provided in this part, nothing contained in this part shall be construed as authorizing any department, agency, officer, or employee of the United States to exercise any direction, supervision, or control over, or impose any requirement or condition with respect to, the research conducted by, and the personnel or administration of, any institution.

REGULATIONS

Sec. 499G. Within 6 months after the date of enactment of this part, the Director, after consultations with the Advisory Council, shall prescribe regulations regarding the eligibility of institutions for grants awarded under this part, and the terms and conditions of approving applications for such grants. The Director may prescribe such other regulations as the Director finds necessary to carry out this part.

PEER REVIEW OF APPLICATIONS

Sec. 499H. (a) In General.—The Director shall require appropriate peer review of applications for grants under this part in accordance with section 492.

(b) Manner of Review.—Review of grant applications shall be conducted in a manner consistent with the system of scientific peer

review conducted by scholars with regard to applications for grants under this Act for biomedical and behavioral research.

(c) MEMBERSHIP.—Members of the peer review group estabished by the Director under section 499B shall be individuals who by the virtue of their training or experience are eminently qualified to perform review functions, except that not more than one-fourth of the members of any peer review group shall be officers or employees of the United States.

AUTHORIZATION OF APPROPRIATIONS

SEC. 499I. There are authorized to be appropriated to award grants and carry out this part $150,000,000 for fiscal year 1989 and such sums as necessary for each of the fiscal years 1990 and 1991. Sums appropriated pursuant to this section shall remain available until expended.

DEFINITIONS

SEC. 499J. As used in this part:

(1) CONSTRUCTION AND COST OF CONSTRUCTION.—The terms "construction" and "cost of construction" include the construction of new buildings and the expansion, renovation, remodeling, and alteration of existing buildings, including architects' fees, but not including the cost of acquisition of land or offsite improvements.

(2) PUBLIC OR NONPROFIT PRIVATE INSTITUTION.—The term "public or nonprofit private institution" means an institution that conducts biomedical or behavioral research, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

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